

Medicare Prescription Drug Benefit Manual

Chapter 6 – Part D Drugs and Formulary Requirements

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10 - Definition of a Part D Drug

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D drugs are defined in Title XVIII of the Social Security Act (the Act) and in the regulations ([42 CFR §423.100](#)). Part D sponsors are responsible for making appropriate coverage determinations and ensuring that covered Part D drugs meet the requirements in this section.

10.1 - General

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Subject to the exclusions specified in section 20 of this chapter, a Part D drug means *the following, if* used for a medically-accepted indication as defined by section 1927(k)(6) of the Act:

- A drug *that may be dispensed only upon a prescription* that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;
- A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;
- Insulin described in section 1927(k)(2)(C) of the Act;
- Medical supplies associated with the delivery of insulin;
- A vaccine licensed under section 351 of the Public Health Service Act and its administration.

*The Centers for Medicare & Medicaid Services (CMS) considers it best practice for Part D sponsors to consider the proper listing of a drug product with the **Food and Drug Administration (FDA)** as a prerequisite for making a Part D drug coverage determination. The FDA is unable to provide regulatory status determinations through their regular processes if a drug product is not properly listed. Therefore, Part D sponsors should begin the drug coverage determination process by confirming that a prescription drug product national drug code (NDC) is properly listed with the FDA. *The FDA's Comprehensive NDC Structured Product Labeling Data Elements file (NSDE) is used as a source of NDC information for Medicare Part D Formulary Reference File and prescription drug event (PDE) editing. The NSDE file can be found at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm>**

CMS interprets “dispensed only upon a prescription” as meaning a drug that is recognized by the **FDA** as a prescribed drug requiring “Rx only” on its label per section 503(b)(4) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Additionally, Part D sponsors must recognize a physician’s authority to delegate prescribing where authorized by State law. Generally, in retail pharmacy, standing orders and protocols are methods used by physicians to delegate and define their prescribing authority to non-physician providers such as pharmacists. Standing orders are typically pre-approved documents for a specific drug or vaccine, contain a set of required clinical criteria and permit administration of

the drug without physician examination, as long as the required clinical criteria are met. A protocol is similar to a standing order but is generally broader in scope and may include multiple drugs and extensive clinical criteria. *A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription, as required by §423.104(h).*

10.2 - Covered Part D Drug

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

A covered Part D drug is a Part D drug that is included in a Part D sponsor's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under 42 CFR §§423.566, 423.580, and 423.600, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with 42 CFR §423.124. *For the applicable drugs of a manufacturer to be covered under Part D, the manufacturer must participate in the Medicare Coverage Gap Discount Program. An applicable drug is a Part D drug that is approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or a biologics license application under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such Act). Thus the definition of applicable drugs excludes biological products approved under the abbreviated licensure pathway (biosimilars).*

10.3 - Commercially Available Combination Products

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Only those combination products approved and regulated in their combination form by the FDA as a drug, vaccine, insulin, or biological product, as described in paragraph (i), (ii), (iii), or (v) of the Part D drug definition at §423.100 are eligible for Part D coverage. This requirement for FDA approval applies to commercially available combination products meant for broad distribution. Extemporaneously compounded prescription drug products (addressed separately in this chapter in section 10.4 as well as in §423.120(d)) are not affected by this requirement. Approved commercially available combination products include those with multiple active ingredients combined in a single drug product and those products with multiple drugs that remain separate but are co-packaged together and intended for dispensing as a single entity.

10.4 - Extemporaneous Compounds

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Compounded prescription drug products can contain: (1) all Part D drug product components; (2) some Part D drug product components; or (3) no Part D drug product components. *As defined in §423.120(d), only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not contain any ingredients covered under Part B as prescribed and dispensed or administered, may be covered under Part D.* Only costs associated with those components that satisfy the definition of a Part D drug are allowable costs under Part D because the compounded products as a whole do not satisfy the definition of a Part D drug.

For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary. Bulk powders (i.e., Active

Pharmaceutical Ingredients for compounding) do not satisfy the definition of a Part D drug and are not covered by Part D. For any non-Part D ingredient of the Part D compound, the Part D sponsor's contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.

Sponsors treating compounds as non-formulary products should be applying the cost sharing associated with an exceptions tier, regardless of whether the compound contains brand name or generic products. For a Part D compound considered off-formulary, transition rules apply such that all ingredients that independently meet the definition of a Part D drug must become payable in the event of a transition fill and be covered if an exception under [§423.578\(b\)](#) is approved for coverage of the compound.

The labor costs associated with mixing a compounded product that contains at least one Part D drug component can be included in the dispensing fee (as defined in [42 CFR §423.100](#)). For compounds containing all generic products, the generic cost-sharing should be applied. If a compound contains any brand name products, the Part D sponsor may apply the higher brand name cost-sharing to the entire compound. *For low income subsidy (LIS) beneficiaries the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug.*

10.5 - Medical Supplies Associated with the Delivery of Insulin (Rev. 2; Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes, can satisfy the definition of a Part D drug. However, test strips, lancets and needle disposal systems are not considered medical supplies directly associated with the delivery of insulin for purposes of coverage under Part D.

Insulin syringes equipped with a safe needle device, in their entirety (syringe and device), are also Part D drugs and should be managed like any other Part D drug the sponsor places on its formulary. Part D sponsors must make safety enabled insulin syringes available on their formularies for all of their institutionalized beneficiaries.

10.6 - Medically-Accepted Indication

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Section 1860D-2(e)(4) of the Act *defines* “medically-accepted indication,” *in part* by reference to section 1927(k)(6) of the Act, to any use of a covered Part D drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. The *recognized* compendia are:

- I. American Hospital Formulary Service Drug Information, *and*
- II. DRUGDEX® Information System.

The definition of medically accepted indication also means, in the case of a covered Part D drug used in an anticancer chemotherapeutic regimen, the definition of medically accepted indication in section 1861(t)(2)(B) of the Act. Thus, Part D sponsors will be required to thoroughly understand and apply Part B's definition of an anti-cancer chemotherapeutic regimen, utilize Part B compendia, and consider peer reviewed medical literature when necessary. Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 50.4.5 (<http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>) will be the authoritative guidance for Part D sponsors in their consideration of medically-accepted indications for Part D anti-cancer chemotherapeutic claims.

Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically-accepted indications *using the tools and data available to them to make such determinations. Part D sponsors must reference all CMS recognized compendia to determine whether there are any supportive citations, prior to determining that a drug is not being used for a medically-accepted indication.* Part D sponsors may rely on utilization management policies and procedures, *approved by CMS where required (see section 30.2.2.1),* to make such determinations. *Dispensing pharmacists* are not required to contact each prescriber to verify a prescription is being used for a medically-accepted indication.

Also, medically-accepted indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication. Part D sponsors may have dose limitations based on FDA labeling, but an enrollee may request (and be granted) an exception to a dose restriction through the formulary exception process based on medical necessity criteria.

Additionally a Part D drug must be used for a medically-accepted indication that facilitates the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (except for Part D vaccines). Consequently, if a drug works on medical equipment or devices and is not used for a medically-accepted indication of therapeutic value on the body, it cannot satisfy the definition of a Part D drug. For example, a heparin flush is not used to treat a patient for a medically-accepted indication, but rather to dissolve possible blood clots around an infusion line. Therefore, heparin's use in this instance is not therapeutic but is, instead, necessary to make durable medical equipment work. *Heparin* would therefore not be a Part D drug when used in a heparin flush.

Utilization management edits should be applied to drugs that are likely to be used for indications that are excluded from Part D coverage or that are not medically accepted in the sponsor's experience or as directed by CMS. While CMS would not expect edits to be universally applied to check whether every drug or most drugs are being used for medically-accepted indications, Part D sponsors remain responsible for ensuring that Part D drugs are only covered when used for medically-accepted indications. Therefore, all Part D sponsors should consistently utilize prior authorization (PA) for those drugs with the highest likelihood of non-Part D covered uses, as detailed in section 30.2.2.3 unless plans are able to reliably use tools other than PA to determine appropriate coverage for the drug.

10.6.1 - Retrospective Determination of a Medically-Accepted Indication *(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)*

Part D sponsors may retrospectively identify and confirm – either as part of their retrospective review programs required under 42 CFR §423.153, or incident to another utilization management review – that a dispensed drug, *including when dispensed as a transition fill*, was not prescribed for a medically-accepted indication for a particular individual (see the example below, in which this occurred because a dosage issue resulted in the case being flagged).

Example: An individual receives a prescription and takes *the* drug within a common dosing regimen (i.e., one tablet daily). Several months later, that individual’s physician writes a new prescription for an increased dosage of that drug. The second prescription triggers a quantity limit *claim edit* (for example, based on safety limits). As a result, the individual’s physician *requests a coverage determination from the plan and* submits evidence to support an exception to the quantity limit. Based on that evidence, the Part D sponsor makes a determination that the drug was not prescribed for a medically-accepted indication.

When it was not reasonable to expect a Part D sponsor to require prior authorization to ensure a drug is being used for an accepted medical indication, CMS would not expect the sponsor to recover payments made to pharmacies or attempt to obtain reimbursement from enrollees. However, *when retrospective review of point of sale claims adjudication determines that a drug was dispensed for a non-medically-accepted indication, the PDE should be deleted and accumulators adjusted. (Sponsors should additionally reference all applicable PDE guidance and, when applicable, guidance in the Prescription Drug Benefit Manual, chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals, regarding required notices for coverage determinations, available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip>).*

10.7 - Drugs Purchased in Another Country

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors must exclude Part D drugs from qualified prescription drug coverage if they are not sold in the United States. In addition, Part D sponsors may only pay for drugs that satisfy the definition of Part D drug. In general, such definition requires FDA approval for sale in the United States. Therefore, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved.

In the event of a drug shortage, in order to ensure access to critically needed drugs in conjunction with the actions taken by the FDA, CMS will accept PDE submissions with national drug codes for foreign versions of Part D drugs, imported under the FDA’s exercise of its enforcement discretion. PDE allowances will be limited to the specific drug product(s), conditions, and the duration of the shortage as specified by the FDA. Such products cannot be discounted under the Medicare Coverage Gap Discount Program.

10.8 - Drugs Used to Treat Opioid Dependence

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors must include coverage for Part D drugs, either by formulary inclusion or via an exception, when medically necessary for the treatment of opioid dependence. Coverage is not limited to single entity products such as Subutex®, but must include combination products *that are Part D drugs* when medically necessary (e.g., Suboxone®). For any new enrollees, CMS requires sponsors to have a transition policy to prevent any unintended interruptions in pharmacologic treatment with Part D drugs during their transition into the benefit. This transition policy, along with CMS' non-formulary exceptions/appeals requirements, should ensure that all Medicare enrollees have timely access to their medically necessary Part D drug therapies for opioid dependence.

A Part D drug is defined, in part, as “a drug that may be dispensed only upon a prescription.” Consequently, methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy. **(NOTE:** Methadone is a Part D drug when *used* for pain). State Medicaid Programs may continue to include the costs of methadone in their bundled payment to qualified drug treatment clinics or hospitals that dispense methadone for opioid dependence.

10.9 - DESI Drugs

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

For a drug to be available for reimbursement by a Part D sponsor it must meet the definition of a Part D drug. Section 1860D–2(e)(1) of the Social Security Act (the Act) generally defines a Part D drug to include those drugs that may be dispensed only upon a prescription and that meet the requirements of section 1927(k)(2) of the Act. Section 1927(k)(2) generally requires that the drug be approved by the FDA or otherwise described under sections 1927(k)(2)(A)(ii) or (A)(iii) of the Act. These provisions address those drugs affected by the Drug Amendments of 1962 (amending the Federal Food, Drug & Cosmetic Act), which require that a new drug be proven effective, as well as safe. FDA's Drug Efficacy Study Implementation (DESI) evaluates the effectiveness of those drugs that had been previously approved on safety grounds alone. FDA indicates that these drugs, and those identical, related, and similar to them, may continue to be marketed until the administrative proceedings evaluating their effectiveness have been concluded, at which point continued marketing is permitted only if a new drug application (NDA) or abbreviated new drug application (ANDA) is approved. The vast majority of the DESI proceedings have been concluded, but a few are still pending.

The definition of a Part D drug does not include less than effective (LTE) DESI drugs or those identical, related or similar drugs to the LTE DESI drug. As FDA continues to undertake reviews under the DESI program and announces results of its hearings, CMS would expect Part D sponsors to adjust their formularies accordingly, as they should with any other applicable FDA drug product announcement. If a sponsor discovers the presence of any LTE DESIs on its

formulary based on an FDA announcement or otherwise, it should remove these drugs from the formularies on accordance with section 30.3.¹

10.10 - Over-the-Counter Products (OTCs)

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

The definition of a Part D drug does not include OTCs. Therefore, Part D sponsors cannot cover OTCs under their basic prescription drug benefit or as a supplemental benefit under enhanced alternative coverage. However, CMS will allow Part D sponsors the option to provide OTCs as part of their administrative costs structure. Refer to chapter 7, section 60, of this manual for further discussion of this option.

When an existing formulary product switches to an OTC status during the contract year, any existing inventory of the previous legend product (manufactured under the legend New Drug Application (NDA) and possessing the legend National Drug Code (NDC) number) will continue to satisfy the Part D drug definition. Given the potential for beneficiaries requiring conversion to other therapeutically equivalent legend products, CMS strongly recommends immediate notification of affected enrollees using the notification criteria outlined in section 30.3.4. CMS will direct sponsors to remove the converted legend product from their formulary at the next formulary submission window after the OTC product becomes available.

Providing the OTC product at no cost to beneficiaries, as outlined in chapter 7, section 60, of this manual, will not satisfy CMS' formulary requirements and Part D sponsors may need to add additional drugs when the OTC is removed from its formulary. However, adjudication of the legend product may continue as long as the market holds residual inventory.

10.11 - Common Home Infusion Drugs

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

CMS has identified a list of acute care drugs that are most commonly utilized in the home infusion setting. The use of these drugs or drug classes often results in an earlier hospital discharge and reduced healthcare costs. Rapid access to these agents is imperative for these health care transitions. It is CMS' expectation that Part D sponsors will not implement policies that could potentially delay or restrict beneficiary access to these important agents. In general, should prior authorization or other utilization management edits apply to any of these agents, CMS would expect that Part D sponsors handle these in an expedited manner in order to facilitate hospital discharge in appropriate time frames. In addition, it is CMS' expectation that Part D sponsors ensure appropriate beneficiary access to these drugs or drug classes via formulary inclusion. See Appendix A for a list of commonly utilized home infusion drugs.

¹ If, based on an FDA announcement, a Part D sponsor recognizes and removes a non-Part D drug from its formulary; CMS expects that Part D sponsors will provide 60 days of advance notice of the formulary removal.

10.12 - Bundling of Home Infusion Drugs Under a Part C Supplemental Benefit

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors that offer Medicare Advantage (MA) prescription drug plans may choose to provide Part D home infusion drugs as part of a bundled service as a mandatory supplemental benefit under Part C, provided the sponsor consistently applies the option (i.e., in a given contract year, the plan either always covers a particular home infusion drug as part of a bundled service under Part C, or always covers a particular home infusion drug under Part D). Given uniform benefits requirements, sponsors electing this option must also ensure that the bundled service is available to all enrollees of any MA-PD or cost plan in which it chooses to provide Part D home infusion drugs as a mandatory supplemental benefit under Part C.

Interested Part D sponsors must appropriately assign these costs to the Part C component of their bids to account for these bundled drugs. They must also provide, through the Formulary Submission module, a file that clearly identifies the Part D home infusion drugs that will be offered as part of a mandatory supplemental benefit under Part C for the following contract year. CMS will review sponsors' home infusion drug files as part of our formulary review process to ensure that only home infusion drugs are included as part of the Part C supplemental benefit.

Effective with contract year 2010, CMS *waived* the definition of a Part D drug at [42 CFR §423.100](#) with respect to Part D drugs covered as part of a bundled benefit under a Part C supplemental benefit. Waiver of the definition of a Part D drug will improve benefit coordination of home infusion therapy between Parts C and D, particularly since the services and supplies necessary for home infusion are never covered under Part D but would be provided as part of a bundle of service under a Part C mandatory supplemental benefit. However, this waiver is conditioned on the application of zero cost sharing for the bundle of home infusion services provided under a Part C supplemental benefit. Thus, sponsors will not qualify for the waiver and, in turn, will not qualify to cover Part D home infusion drugs as part of a bundle of services under a Part C supplemental benefit without indicating on their Plan Benefit Packages (PBPs) that the applicable cost sharing for this bundle of services is \$0.

In addition, the requirement that Part D sponsors' formularies include at least two Part D drugs in each category and class of covered Part D drugs at 42 CFR [§423.120\(b\)\(2\)\(i\)](#) is waived for Part D sponsors for applicable formulary categories or classes when Part D home infusion drugs are provided as part of a bundled service as a mandatory supplemental benefit under Part C. Waiver of the requirement at 42 CFR [§423.120\(b\)\(2\)\(i\)](#) will allow Part D sponsors choosing to provide Part D home infusion drugs as a part of bundled service under a Part C mandatory supplemental benefit to improve benefit coordination of home infusion therapy between Part C and Part D. This improved benefit coordination promotes continuity of care and cost avoidance of more expensive institutional care by facilitating continuous access to home infusion drugs, as well as the costs of administration and supplies associated with that therapy.

Part D sponsors choosing to provide Part D home infusion drugs as part of a bundled service must indicate on their marketed formularies that certain drugs may be covered under the

sponsor's medical, rather than its prescription, benefit. For more information, consult the model formulary available at:

<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Marketing-Materials.html>.

10.13 - Inhaler Supplies

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

In general, only those accessories for meter dose inhalers (MDIs), Dry Powder Inhalers (DPIs), or Nasal Spray Inhalers (NS) that are included on the *New Drug Application* or *Abbreviated New Drug Application*, listed on the package insert, and specifically packaged with the drug product itself are eligible to meet the definition of a Part D drug. If the accessories (i.e., actuator, chamber) are sold separately or are not included on the drug product's NDA or ANDA, they would not meet the definition of a Part D drug.

10.14 - Vaccine Administration

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Since January 1, 2008, the Part D program *covers* vaccine administration costs associated with Part D vaccines. CMS interprets this statutory requirement to mean that the Part D vaccine administration costs are a component of the negotiated price for a Part D-covered vaccine. In other words, the negotiated price for a Part D vaccine will be comprised of the vaccine ingredient cost, a dispensing fee (if applicable), and a vaccine administration fee. This interpretation recognizes the intrinsic linkage that exists between the vaccine and its corresponding administration, since a beneficiary would never purchase a vaccine without the expectation that it would be administered.

In general, CMS believes that Part D vaccines, including the associated administration costs, should be billed on one claim for both in- and out-of-network situations. For example, if an in-network pharmacy dispenses and administers the vaccine in accordance with State law, the pharmacy would process a single claim to the Part D sponsor and collect from the enrollee any applicable cost-sharing on the vaccine and its administration. Alternatively, if a vaccine is administered *outside of the plan's Part D pharmacy network*, the *provider* would *supply* the vaccine, *administer it*, and then bill the beneficiary for the entire charge, including all components. The beneficiary would, in turn, submit a paper claim to the Part D sponsor for reimbursement for both the vaccine ingredient cost and administration fee.

10.14.1 - Elements of Vaccine Administration

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Vaccine administration fees should be subject to negotiations between Part D sponsors and pharmacies. CMS expects that sponsors will take into consideration the elements reflected in existing Part B vaccine administration fees when establishing their own vaccine administration fees. For example, Part B considers the immunizing professional's time in physically delivering the vaccine to a beneficiary, the resources encompassing the supplies (syringe, gauze, band-aid, alcohol prep pad, etc.), the indirect costs of the office, and professional liability.

10.14.2 - Establishment of Multiple Vaccine Administration Fees (Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors will have the discretion to implement either a single vaccine administration fee for all vaccines or multiple administration fees based on type of vaccine, variance in provider type, and product administration complexity. CMS plans to retrospectively review vaccine administration fees to look for outliers and potentially discriminatory practices that would impact beneficiary access to Part D vaccines.

10.14.3 - Other Vaccine Administration Considerations (Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors may implement drug utilization management tools to determine if a vaccine is necessary; however, in the absence of any information showing previous immunization (i.e., claims data), the Part D sponsor should make payment available for a vaccine and its administration consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.

20 - Part D Exclusions (Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

20.1 - Excluded Categories (Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D *does not cover* drugs or classes of drugs, or their medical uses, which *are* excluded from coverage or otherwise restricted under section 1927(d)(2) of the Act.

Drugs Excluded from Part D coverage:

- Agents when used for anorexia, weight loss, or weight gain (even if used for a non-cosmetic purpose (i.e., morbid obesity)).
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.

- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Agents when used for the treatment of sexual or erectile dysfunction (ED). ED drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction (such as pulmonary hypertension). **However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information, and DRUGDEX® Information System.**

Drugs Not Excluded from Part D Coverage:

- Prescription drug products that otherwise satisfy the definition of a Part D drug are Part D drugs when used for AIDS wasting and cachexia due to a chronic disease, if these conditions are medically-accepted indications as defined by section 1927(k)(6) of the Act for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia due to a chronic disease as either agents used for weight gain or agents used for cosmetic purposes.
- Part D drugs indicated for the treatment of psoriasis, acne, rosacea, or vitiligo are not considered cosmetic.
- Vitamin D analogs such as calcitriol, doxercalciferol, *and* paricalcitol when used for a medically-accepted indication as defined by section 1927(k)(6) of the Act, are not excluded because CMS interprets the exclusion of prescription vitamin D products as being limited to products consisting of ergocalciferol (vitamin D2) and/or cholecalciferol (vitamin D3).
- Prescription-only smoking cessation products.
- Prescription Niacin Products (Niaspan, Niacor).
- Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and/or colds. For example, when “cough” medications are used *to treat a medical condition that causes a cough, such as the use of bronchodilators for the treatment of bronchospasm in asthma, CMS does not consider these “cough” medications as excluded drugs and, therefore, these medications may be covered under Part D. However, antitussives used to treat cough symptoms, and not the underlying medical condition causing the cough, are excluded from basic Part D coverage regardless of the medical condition causing the cough.*
- *Benzodiazepines*

- *Barbiturates*

See Appendix B for further clarification of Part D coverage or non-coverage of specific products/drugs/drug categories.

20.2 - Drugs Covered Under Medicare Part A or B

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

The Social Security Act specifies that a drug prescribed to a Part D eligible individual cannot be considered a covered Part D drug if payment for such drug “...is available (or would be available but for the application of a deductible) under part A or B for that individual.” CMS interprets this to mean that if payment could be available under Part A (*e.g., hospital inpatient, hospice benefit*) or Part B to the individual for such drug, then it will not be covered under Part D. Consequently, drugs covered under Parts A and B are considered available (and excluded from Part D) if a beneficiary chooses not to pay premiums or if a beneficiary has enrolled in Part B but that coverage has not yet taken effect.

Two unique examples of drugs covered under Part A or B are (1) drugs and biological products related to the terminal illness or related conditions for beneficiaries who have elected the Medicare hospice benefit, as these drugs should be covered under the Medicare Part A payment to a hospice, and (2) drugs used for ESRD beneficiaries receiving renal dialysis services, as these drugs are included in the Medicare Part B bundled payment to an ESRD dialysis facility.

Drugs and biological products paid for under the Medicare Part A per-diem payments to a Medicare hospice program are excluded from coverage under Part D. However, given access and operational issues, in lieu of placing a beneficiary-level PA on all drugs for beneficiaries who have elected hospice, CMS strongly encourages sponsors to only place beneficiary-level PA requirements on the following four categories: analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs (anxiolytics).

Part D sponsors generally may use either PA requirements or a “pay and chase” approach to determine whether payment for drugs may be made under Part D. However, given concerns regarding the impact on access to drugs for ESRD beneficiaries or for those beneficiaries who have elected hospice, sponsors are strongly encouraged to limit the use of PA to certain specific categories of drugs covered under the Medicare hospice benefit or drugs that are always used for the treatment of ESRD for ESRD beneficiaries receiving renal dialysis services. Further, recent CMS guidance pertaining to these drugs indicates sponsors are not expected to take special measures beyond their normal compliance and utilization review activities to retrospectively review paid claims for purposes of determining whether drugs in the other categories were either unrelated to the hospice beneficiary’s terminal illness or used for ESRD treatment. However, if it is determined through routine utilization review or otherwise that a drug has been inappropriately billed to a Part D sponsor, the Part D sponsor should seek recovery from the hospice provider, ESRD dialysis facility, or beneficiary, as appropriate.

See Appendix C for further explanation and clarification of specific issues regarding coverage under Medicare Part B.

20.2.1 - Exhausted Part A Benefits

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

The issue of applicability of Part D coverage has also arisen in the context of inpatients in acute care hospital settings (including long-term care (LTC) hospitals, which are certified as acute care hospitals) who have exhausted their Part A inpatient stay benefit, but who require and continue to receive a level of care that qualifies them for a Part A inpatient stay.

Drugs provided in an inpatient setting to an individual who has exhausted his or her lifetime inpatient hospital benefit under Part A are not drugs that could be covered under Part A for that individual. Unlike a beneficiary who, for example, chooses not to buy into Part B, there is no way for an individual who has exhausted his or her Part A inpatient stay benefit to obtain coverage under Part A for his or her drugs; therefore, Part D coverage may be available to a Part D enrollee who has exhausted his or her Part A inpatient stay benefit and who remains in that inpatient setting (provided the drug would otherwise be covered under Part D). See chapter 5, section 50.5.4, regarding sponsor contracting requirements when a beneficiary has exhausted inpatient Part A benefit days.

20.2.2 - Part D Sponsor Due Diligence in Prior Authorization of Part *A or B* Versus Part D Coverage Determination

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

A drug approved or denied through prior authorization constitutes a coverage determination, subject to all applicable coverage determination standards, timelines, and requirements. However, Part D sponsors should rely upon (1) information included by the physician with the prescription, (2) information communicated by the pharmacist or included with the submitted claim, such as diagnosis information (e.g., to determine whether the prescription is related to a Medicare covered transplant), (3) information captured by the plan sponsor previously, such as diagnosis information from previous PAs, and (4) location of administration (e.g., to determine if the prescription is being dispensed for a beneficiary in a nursing home) when available to avoid the need for a separate coverage determination request to obtain the needed information whenever possible. Assuming the available information is sufficient to correctly assign payment to Part A or B or Part D, there is no need in such cases to require additional information to be obtained from the physician.

To the extent that the Part D sponsor requires its contracted pharmacies to report the information provided on the prescription to assist in the determination of Part *A or B* versus Part D coverage, the sponsor *should* rely on the pharmacist's report of appropriate information to *appropriately adjudicate the claim* under Part D. For example, for cases in which prednisone is prescribed for a condition other than immunosuppression secondary to a Medicare-covered transplant, and this is *either documented* on the prescription, *or evident based on the prescriber's specialty, a known diagnosis, or concomitant therapies*, a sponsor may cover the drug under Part D without seeking further information from the prescribing physician.

This clarification should not be construed to indicate that a Part D sponsor may not impose prior authorization or other procedures to ensure appropriate coverage under the Medicare drug benefit. *Part D sponsors may apply prior authorization to establish appropriate payment under Part A or B or Part D, even if the beneficiary is currently taking the drug.* However, CMS believes that the sponsor will have met appropriate due diligence standards without further contacting a physician if necessary and sufficient information is *available*, and the contracted pharmacy is able to communicate this information to the sponsor in order to make the coverage determination. *Refer to section 30.2.2.3 for additional guidance on the application of PAs. For more information on Coverage Determination requirements, see Medicare Prescription Drug Benefit Manual, chapter 18, available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip>.*

20.3 - Coverage of Supplemental Drugs Under Enhanced Alternative Coverage

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

A Part D sponsor may *only* include coverage of drugs that would meet the definition of a Part D drug but for the application of section 20.1 (these are known as “supplemental drugs,” as provided in *chapter 5*, section 10.2 of this manual) as a supplemental benefit under enhanced alternative coverage.

20.4 - Application of General Exclusion Provisions

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

In accordance with section 1860D-2(e)(3) of the Act, a Part D sponsor may exclude from qualified prescription drug coverage any Part D drug:

- For which payment would not be made if items and services are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (except for Part D vaccines); or
- Which is not prescribed in accordance with the Part D *plan*.

Such exclusions are coverage determinations *or redeterminations pursuant to chapter 18 of this manual, and are* subject to appeal.

Unlike other Part D drugs that may be excluded when not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Part D vaccines may only be excluded when their administration is not reasonable and necessary for the prevention of illness.

30 - Formulary Requirements

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet requirements for the following:

- Pharmacy and Therapeutics committee;
- Provision of an adequate formulary;
- Transition process;
- Limitation on changes in therapeutic classification;
- Provision of notice regarding formulary changes;
- Limitation of formulary changes prior to beginning of contract year;
- Provider and patient education; and
- Formulary changes during the contract year.

30.1 - Pharmacy and Therapeutics (P&T) Committee (Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor's formulary must be developed and reviewed by a P&T committee that meets specific requirements with respect to:

- Membership;
- Conflict of interest;
- P&T member disclosure to CMS;
- Meeting administration;
- Formulary management;
- Formulary exceptions; and
- P&T committee role.

30.1.1 - Membership (Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors' P&T committee membership must satisfy the following requirements:

- P&T committee members must come from various clinical specialties that adequately represent the needs of sponsors' enrollees.
- A majority of the P&T committee members must be practicing physicians, practicing pharmacists, or both. *CMS defines a practicing physician or pharmacist to be an individual who has an active professional license to practice in the United States or one of its Territories and is currently practicing in the U.S. or one of its Territories.*
- At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons.
- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the Part D sponsor and pharmaceutical

manufacturers. Such P&T committee members may have certain non-employee relationships with pharmaceutical manufacturers (for example consulting, advisory, or research relationships) and still be considered independent and free of conflict provided those relationships do not constitute significant sources of income and they do not otherwise have a conflict of interest that would compromise their independence. In addition, panel providers in a staff model HMO may be considered independent and free of conflict to the extent that any remuneration received from a Part D sponsor is limited to his or her clinical responsibilities for the care of plan enrollees.

30.1.2 - Conflict of Interest

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

P&T committee members should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions.

30.1.3 - P&T Committee Member Disclosure to CMS

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

In the event the Part D sponsor has entered into a confidential agreement such that the Pharmacy Benefits Manager (PBM) will not disclose its P&T committee membership to the Part D sponsor, then it is the Part D sponsor's responsibility to notify CMS that this information will be submitted by the sponsor's PBM. Moreover, the Part D sponsor must ensure that the PBM notifies CMS of the P&T committee membership. The Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract and the sponsor must ensure that the PBM notifies the sponsor that this information has been successfully submitted to CMS.

30.1.4 - Meeting Administration

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

The Part D sponsor's P&T committee should meet on a regular basis, but no less than quarterly. P&T committee decisions regarding formulary development or revision must be documented in writing.

30.1.5 - Formulary Management

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsor's P&T committee will consider the following:

- The P&T committee must review for clinical appropriateness the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions, and other drug utilization activities that affect access. P&T committee recommendations regarding these activities are advisory only and not binding on the Part D sponsor.

- Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost effective drug therapy.
- The P&T committees will be required to establish and document procedures to ensure appropriate drug review and inclusion. This includes documentation of decisions regarding formulary development and revision and utilization management activities (42 CFR §423.120(b)(1)(viii)). P&T committee recommendations regarding which Part D drugs are placed on a sponsor's formulary are binding on the Part D sponsor.
- Clinical decisions by the P&T committee should be based on scientific evidence and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines, and pharmacoeconomic studies, as well as other sources of appropriate information.
- Drugs' therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them on formulary tiers.
- The P&T committee will make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days *of its release onto the market* and will make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met.
- The P&T committee will evaluate and analyze treatment protocols and procedures related to the sponsor's formulary at least annually.
- The P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.
- Part D sponsors that change *pharmacy benefit managers (PBMs)* mid-year are required to continue the existing formulary. Decisions regarding formulary inclusion made by the previous PBM's P&T committee are binding on the assuming PBM. CMS will not approve negative formulary change requests for the purpose of aligning an existing formulary with that of a new PBM.

30.1.6 - Formulary Exceptions

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

P&T committees must review for clinical appropriateness protocols and procedures for the timely use of and access to both formulary and non-formulary drug products. Part D coverage determinations and appeals information can be found in chapter 18 of this manual.

30.1.7 - P&T Committee Role in Transition

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

At a minimum, a sponsor's transition process, the minimum requirements of which are detailed in section 30.4, will address procedures for medical review of non formulary drug requests and, when appropriate, a process for switching new Part D sponsor enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. CMS will look to transition process submissions for assurances that a sponsor's P&T committee will review and provide recommendations regarding the procedures for medical review of non-formulary drug requests. P&T committee involvement will help ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs that are not on the sponsor's formulary (or that are on the formulary but require prior authorization or step therapy under a sponsor's utilization management requirements) and which are known to have risks associated with any changes in the prescribed regimen.

30.2 - Provision of an Adequate Formulary

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

CMS encourages Part D sponsors to submit formularies similar to those in widespread use today. CMS will check the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, in order to satisfy the Medicare Modernization Act (MMA) requirement that a sponsor's categorization system does not substantially discourage enrollment by any group of beneficiaries. CMS will consider the specific drugs, tiering and utilization management strategies employed in each formulary. CMS will identify outliers from common benefit management practices for further evaluation. Sponsors may be asked to provide written clinical justification for unusual benefit features that are identified as outliers.

30.2.1 - Formulary Categories and Classes

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D formularies must include drug categories and classes that cover disease states, *consistent with Part D program requirements*. CMS will evaluate the sufficiency of a Part D sponsor's formulary categories and classes in conjunction with the formulary drug list to ensure that the formulary provides access to an acceptable range of Part D drug choices.

Part D sponsors *may use existing classification systems, such as those from U.S. Pharmacopeia (USP) and American Hospital Formulary Service (AHFS), or create their own*. CMS will *automatically* approve formulary classification *systems that are* consistent with the USP classification system, available at www.usp.org. For sponsors that choose to adopt an alternative classification structure, CMS will check the sponsor's proposed classification system to determine if it is similar to USP or other commonly used classification systems, such as the AHFS Pharmacologic-Therapeutic Classification (information available at <http://www.ahfsdruginformation.com/pt-classification-system.aspx>).

Each category or class must include at least two drugs (unless only one drug is available for a particular category or class, or only two drugs are available but one drug is clinically superior to the other for a particular category or class), regardless of the classification system that is utilized. The two drug minimum requirement must be met through the provision of two chemically distinct drugs. In other words, Part D sponsors will not meet this requirement by including only

two dosage forms or strengths of the same drug, or a brand name drug and its generic equivalent. Aside from the inclusion of two drugs in each category or class, multiple strengths and dosage forms should also be available for each covered drug. This should encompass dosage forms used commonly in *long term care* (LTC) facilities and home infusion.

CMS may require more than two drugs for particular categories or classes if additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the sponsor's formulary would substantially discourage enrollment by beneficiaries with certain disease states.

30.2.1.1 - Application of Existing or New Drugs into the Current Version of the USP Model Guidelines

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

For those formularies that utilize the USP Model Guidelines classification structure, there are several methods to accommodate new Part D drugs that come on to the market during the contract *years between revisions of the Guidelines*. These methods may also be utilized to accommodate existing Part D drugs that *have not been* classified under the USP Model Guidelines. CMS expects one of the four options listed below to be used for the above mentioned situations.

1. Addition of a Part D drug into an existing USP category or class. In the event that a new Part D drug is approved and is to be added to the formulary, the newly approved Part D drug may fit into the current classification system. For instance, if a new protease inhibitor is approved, this drug would be added to the formulary in the USP Antivirals category, under the Anti-HIV Agents, Protease Inhibitors class.
2. Placement of a Part D drug into an "Other" class. In the current USP Model Guidelines, USP listed an "Other" class under various categories. Should a new Part D drug receive approval that cannot be placed into an existing class, and the particular USP category contains an "Other" class, the new drug may be placed into the "Other" class.
3. Addition of a new class under an existing category. If a new Part D drug is approved that does not fit into an existing class, but is appropriate for a particular category, then a new class may be displayed under an existing category. This method would also apply to formularies that utilize AHFS or another classification structure.
4. Miscellaneous Therapeutic Agents. If an existing or newly approved Part D drug does not fit into any existing category, a "Miscellaneous Therapeutic Agents" category may be displayed on the formulary.

30.2.2 - Formulary Benefit Management Tools

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

CMS will look to existing best practices to check that Part D sponsors' use of prior authorization, step therapy, and quantity limits is consistent with such practices. CMS will look to current

industry standards as well as appropriate guidelines that might be found from expert organizations and to the use of such standards in existing drug sponsors that are widely used by seniors and people with disabilities. CMS will ensure that sponsors' use of such tools is consistent with best practices. CMS will also compare formularies among the applicants to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits. In cases where a sponsor may fall outside of best practices, the sponsor will be asked to provide a reasonable justification for its practices.

CMS' expectation is that formulary benefit management tools will be used in Part D formularies consistent with the way they are applied in existing formulary systems.

A POS edit that is triggered based on approved formulary criteria or other allowable CMS restriction does not constitute a coverage determination unless the plan treats the presentation of a prescription as a request for a coverage determination. However, a plan that approves or denies a drug through application of such criteria has made a coverage determination that is subject to all applicable coverage determination standards, timelines, and requirements outlined in chapter 18 of this manual, available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip>.

In addition, in accordance with chapter 18 of this manual, when a prescription cannot be filled as written under the Part D benefit and the issue is not resolved at the POS, the network pharmacy must deliver written notice to the enrollee explaining their right to request a coverage determination, including an exception, from the plan. Regardless of whether the plan approves the request, a pharmacist may decide not to dispense a prescription based on the information obtained in a safety edit and/or on his or her professional judgment pursuant to professional standards of practice.

30.2.2.1 - Utilization Management Edits *Requiring CMS Submission and Approval* ***(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)***

CMS *requires* Part D sponsors to submit utilization management requirements *applied at point of sale (POS)*, such as prior authorization (*PA*), step therapy (*ST*), and quantity limits (*QL*) not based upon the FDA's maximum daily dose limits, as part of their Health Plan Management System (HPMS) formulary submission.

Sponsors must perform adequate oversight of their PBMs and other delegated entities to verify that they are complying with all CMS requirements and not causing beneficiary harm due to impermissible delayed or denied access to Part D drugs. A plan may decide that it is reasonable in certain circumstances to accept information from pharmacists, such as in making A or B versus D determinations (see section 20.2.2). CMS encourages sponsors to test the adjudication of their approved formularies and UM edits in advance and during the plan year to help identify errors. In addition, sponsors should routinely review rejected claims to assist in the timely identification of discrepancies between the CMS approved benefit and what is being adjudicated at POS.

There are three types of POS edits²:

- Hard reject: stops the pharmacy from processing a claim unless or until an override is entered or authorized by a plan representative.*
- Soft reject: stops the pharmacy from processing a claim unless or until a pharmacist-submitted drug utilization review (DUR)/prospective payment system (PPS) code is entered. It is important to distinguish that soft edits that have been overridden by the pharmacist cannot later be overturned by the plan.*
- Message only alerts: do not stop a claim from processing, but provide important clinical and/or coverage information to the pharmacy.*

Prior Authorization and Step Therapy Edits

With respect to PAs and STs, sponsors must clearly submit all requirements as part of the respective HPMS files. For example, CMS expects that, with rare exceptions, the sponsor's approval of a PA or ST for one strength of a drug for a beneficiary will apply to all strengths. If the criteria are not submitted to and approved by CMS at a dose-specific level, sponsors must not implement dose-level requirements because this causes undue burden for the beneficiary, pharmacy, and prescriber. Additionally, CMS expects that the Part D sponsor will submit all components of the PA, such as a requirement for laboratory tests and/or other medical procedures before coverage of a drug will be authorized. For more detailed information on applying PA edits, see section 30.2.2.3.

Quantity Limit Edits

While QLs that allow for the dispensing of a given drug up to the FDA-approved maximum daily dose do not need to be submitted to CMS, any QLs enforced below the FDA-approved maximum dose or below the days' supply entered in the Part D benefit package (PBP) must be included in the HPMS formulary submission for CMS review and approval. QL edits may be applied across a plan or applied to a subset population (such as a specific age range for which a drug may be high risk or contraindicated) when clinically appropriate. QL edits may be enforced as maximum daily dose or as quantity-over-time limits, consistent with how they were included in the formulary submission.

High Cost Edits

Part D sponsors may also utilize a POS high cost edit as a component of their comprehensive fraud, waste & abuse program. The use of this edit must not inappropriately restrict access to Part D drugs. CMS expects high cost edits:

- To be resolvable in real time at the POS*
- Not be invoked repetitively for the same drug and dosage dispensed by the same pharmacy or after a favorable coverage determination.*

² Section 12.3 DUR/PPS-Generated Rejections. Telecommunication Version D and Above Questions, Answers, and Editorial Updates. May 2014. National Council for Prescription Drug Programs. Version 26.0.

Once a high cost edit is addressed, should other CMS-approved or other safety edits apply, these edits must also be addressed.

Opioid Specific Safety Edits

Sponsors may apply QLs to opioids even though there is no clearly defined FDA maximum dose in the approved labeling. Overutilization may trigger a plan-level POS edit, which is implemented by a plan after case management and advance written notice, in accordance with the opioid overutilization guidance available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>.

Sponsors are also encouraged to implement plan-level POS edits based upon cumulative morphine equivalent dose (MED) across the opioid class. To do so, plans will need to submit QLs for all individual opioids based upon equivalent MED as part of the HPMS formulary submission for CMS review, unless a lower plan-level (non-cumulative) edit has been approved for a specific opioid. In addition to the HPMS formulary submission reflecting these MED edits, plan sponsors are expected to submit detailed operational information in advance of the formulary submission deadline. The documentation should contain at a minimum the MED level being utilized, and a written description of the mechanics of the programs, such as the days in excess of a cumulative level that would trigger the edit, and the mechanism by which the edits would be resolved. In the event a beneficiary-level POS edit is more limited than a plan-level POS edit, the beneficiary-specific edit should be applied. Utilization management requirements for non-formulary opioid prescriptions should be addressed as part of the coverage determination process.

See section 30.4.8 for additional guidance on edits applied during the transition period. Chapter 7 of this manual contains more information on drug utilization management tools.

30.2.2.2 - Utilization Management Edits Not Requiring CMS Submission and Approval

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

CMS considers safety edits to prevent dispensing of unsafe dosing of drugs to be part of the concurrent DUR requirements for all Part D drugs. CMS does not require Part D sponsors to submit POS safety related edits as part of their HPMS formulary submission, even if they are implemented as hard edits (with the exception of opioid specific edits, as defined in section 30.2.2.1). These edits are typically applied at the point-of-sale or point-of-distribution and assist the pharmacist in identifying and/or preventing inappropriate drug therapy.

These utilization review edits include the following:

- Screening for potential drug therapy problems due to therapeutic duplication;*
- Age/gender-related contraindications;*
- Over-utilization (e.g., early refill) and underutilization;*
- Drug-drug interactions;*
- Incorrect drug dosage or duration of drug therapy (e.g., doses above FDA maximum approved dosing);*

- *Drug-allergy contraindications;*
- *Clinical Abuse/Misuse*

Safety edits, including on protected class drugs and controlled substances, can be implemented without submission to or approval by CMS for duplicative therapy or when labeling clearly indicates the dispensing as unsafe, duplicative, or contraindicated. Edits based upon precautions in the label, as opposed to contraindications or doses that exceed those supported by the label, must be submitted to CMS for approval. These safety controls at POS should not be suppressed during beneficiaries' transition periods (see section 30.4.8- Edits for Transition Fills).

CMS specifically expects all sponsors to consider the cumulative acetaminophen (APAP) content of combination opioid analgesics and implement plan-level edits in their systems to prevent the dispensing of unsafe daily doses of APAP (greater than 4 grams/day as recommended by the FDA). At a minimum, CMS expects Part D sponsors to implement soft plan-level safety edits at POS to reduce cumulative APAP overutilization among enrollees. Sponsors' P&T committees should develop the specifications for plan-level POS edits to prevent cumulative APAP overutilization based upon their own enrollee data, while minimizing false positives by accounting for known exceptions, such as reasonable early refills. P&T committees may consider a mix of plan-level soft edits designed to compel the pharmacist's clinical evaluation of APAP usage and hard edits to prevent APAP doses at and above amounts for which there would be no reasonable medical or dispensing explanation.

30.2.2.3 – Application of Prior Authorization (Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors should consistently utilize PA for those drugs with the highest likelihood of non-Part D covered uses, based on the following definitions:

- *High likelihood that coverage is available under Parts A or B (versus D) for the drug as prescribed and dispensed or administered, as discussed in section 20.2 of this chapter,*
- *High likelihood that the drug is excluded from Part D coverage (e.g., a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1927(d)(2) of the Act), or*
- *High likelihood of use for non-medically accepted indications as defined in section 1860D-2(E)(4) of the Act (see section 10.6).*

CMS recognizes that sponsors utilize standard PA forms to facilitate the collection of information necessary to fulfill the PA. However, CMS has identified several non-allowable practices that cannot be included on prior authorization forms, examples of which are provided below:

- *Requirements more restrictive than CMS-approved prior authorization criteria.*

- *Limited Access or Step Therapy restrictions not consistent with the CMS-approved formulary.*
- *Quantity Limits inconsistent with FDA maximum dosing or not consistent with the CMS-approved formulary.*
- *Prior Authorization criteria not submitted for HPMS approved formulary medications.*
- *Steering of physicians or beneficiaries to a sponsor's and/or PBM's own mail order pharmacy.*

Steering of physicians or beneficiaries to a sponsor's and/or PBM's own specialty pharmacy for any drugs which are not restricted to select pharmacies based on manufacturer or FDA distribution limitations.

30.2.3 - Long-term Care Accessibility

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors will be required to provide medically necessary prescription drug treatments for enrollees in the general Medicare population, as well as those enrollees who reside in LTC facilities. For example, it is CMS' expectation that sponsors provide coverage of dosage forms of drugs that are widely utilized in the LTC setting, such as unit dose products and liquid, chewable, and parenteral preparations. Further, while nebulized solutions may not be required on all formularies, CMS would expect sponsors to also cover these dosage forms under circumstances in which Part B coverage is not available. When determining days supplies for residents in LTC facilities, Part D sponsors should follow industry best practices and allow for at least 31 days per fill.

30.2.4 - Specialty Tiers

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Regulations at 42 CFR §423.578(a)(7) allow Part D sponsors to exempt a formulary tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. In order to ensure that a Part D sponsor does not substantially discourage enrollment by specific patient populations reliant upon these medications, CMS will only approve specialty tiers within formularies and benefit designs that comply with the following:

- Only one tier is designated a specialty tier exempt from cost-sharing exceptions.
- Cost-sharing associated with the specialty tier is limited to 25% after the *standard* deductible and before the initial coverage limit (or *up to 33%* for sponsors with decreased or no deductible under alternative prescription drug coverage designs). *When applying a reduced deductible, sponsors are limited to the maximum specialty coinsurance levels as defined each year in the Bid User Manual. The deductible applied to the non-specialty tiers may not exceed the deductible that is applied to the specialty tier.*

- Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month amount established by CMS in the annual Call Letter may be placed in the specialty tier. CMS will apply an upfront evaluation across all plans for drugs that exceed the dollar-per-month threshold and are intended for inclusion in the specialty tier.
- If not all drugs (including all strengths) within a category or class meet the criteria for inclusion in the specialty tier, the sponsor must ensure that placement of the remaining drugs among the other tiers of the formulary does not substantially discourage enrollment.

Part D sponsors will need to evaluate the negotiated prices at the drug product strength, package size, and formulation level in order to determine appropriate inclusion of the drug in the Part D plan's specialty tier. *In addition to cost calculations, CMS considers claims history in reviewing the placement of drugs on Part D sponsors' specialty tiers. Except for newly approved drugs for which Part D sponsors would have little or no claims data, CMS will approve specialty tiers that only include drugs when their claims data demonstrates that the majority of the fills exceed the specialty tier cost criteria. Part D sponsors should be prepared to provide CMS with the applicable claims data during the formulary review process if requested. Also, if a Part D drug product is available in multiple strengths, package sizes, and formulations, CMS will only allow inclusion on the specialty tier of those strengths, package sizes, and formulations that would reasonably exceed the dollar-per-month threshold.*

Part D sponsors must evaluate the long acting nature of some drug formulations and calculate the monthly cost across the drug's full duration of action *in considering possible specialty tier placement*. For example, if the specialty tier threshold was \$600 dollars, a long acting formulation with a plan negotiated price of \$900 dollars that lasts for 3 months would not be eligible for the plan's specialty tier since the monthly cost is only \$300 dollars.

30.2.5 - Protected Classes

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsor formularies must include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.

Formularies must include substantially all drugs in these six categories that are FDA approved by the last CMS specified HPMS formulary upload date for the upcoming contract year. New drugs or newly approved uses for drugs within the six classes that come onto the market after the CMS specified formulary upload date will be subject to an expedited P&T committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement. At the end of the 90 day period, these drugs must be added to Part D plan formularies.

“Substantially all” in this context means that all drugs and unique dosage forms in these categories are expected to be included in sponsor formularies, with the following exceptions:

- multi-source brands of the identical molecular structure;
- extended release products when the immediate-release product is included;
- products that have the same active ingredient or moiety; and
- dosage forms that do not provide a unique route of administration (e.g., tablets and capsules versus tablets and transdermals);

Part D sponsors may not implement PA or ST requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug. This prohibition applies to those beneficiaries already enrolled in the plan as well as new enrollees who were actively taking drugs in any of the six classes of clinical concern prior to enrollment into the plan. If a sponsor cannot determine at the point of sale *whether* an enrollee is currently taking a drug (e.g., new enrollee filling a prescription for the first time), *the* sponsor shall treat such enrollee as currently taking the drug.

For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models. Part D sponsors may conduct consultations with physicians regarding treatment options and outcomes in all cases.

See also sections 30.2.2.2, 30.2.2.3, 30.4.3, and 30.4.8 of this chapter for additional guidance on utilization management and transition fill guidance specific to protected class drugs.

30.2.6 - Submission of Multiple Formularies

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

CMS recognizes that sponsors may wish to submit more than one formulary in order to offer enhanced access to Part D drugs. CMS has the responsibility to ensure that there are meaningful differences between multiple formulary submissions from one organization to reduce confusion amongst beneficiaries. CMS may request that sponsors withdraw a formulary in which no meaningful differences can be demonstrated.

For guidance on submitting formularies for employer group waiver plans, see chapter 12, section 20.14, of this manual.

30.2.7 - Formulary Performance and Content Review

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Regardless of the classification system chosen, CMS will review and approve drug lists that are consistent with best practice formularies currently in widespread use today. The current formulary requirements are subject to change and/or revision.

CMS *reviews* formulary drug lists *with respect to* the following *areas*:

- *CMS evaluates the sufficiency of a Part D sponsor's formulary categories and classes in conjunction with the formulary drug list to ensure that the formulary provides access to an acceptable range of Part D drug choices.*
- *Consistent with 42 CFR §423.120(b)(2)(i), each formulary is reviewed for inclusion of at least two Part D drugs for each category and class submitted on the formulary file (except as noted in §423.120(b)(ii)).*
- CMS will review tier placement to ensure that the formulary does not substantially discourage enrollment of certain beneficiaries. When developing their formulary tier structure, sponsors should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any subsequent tiers within the formulary structure will be higher cost-sharing tiers in ascending order, *except that plans may assign a low cost share to Tier 5 or 6 when assigned as a Select Care tier.* For example, drugs in Tier 3 will have a higher cost-share for beneficiaries than drugs in Tier 2. Best practices in existing formularies and preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary. The CMS review will focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.
- CMS will analyze formularies to determine whether appropriate access is afforded to drugs or drug classes addressed in widely accepted treatment guidelines which are indicative of general best practice. Examples of these may include asthma, diabetes, chronic stable angina, atrial fibrillation, heart failure, thrombosis, lipid disorders, hypertension, chronic obstructive pulmonary disease, dementia, depression, bipolar disorder, schizophrenia, benign prostatic hyperplasia, osteoporosis, migraine, gastroesophageal reflux disease, epilepsy, Parkinson's disease, end stage renal disease, hepatitis, tuberculosis, community acquired pneumonia, rheumatoid arthritis, multiple sclerosis and HIV. Part D sponsors should be aware of treatment guidelines impacting those enrollees residing in LTC facilities, such as CDC's annual Morbidity and Mortality Weekly Report (MMWR) on prevention and control of influenza. This list of conditions does not represent an exhaustive list, but merely serves as another check in the review process.
- CMS will analyze the availability of the most commonly prescribed drug classes for the Medicare population (Appendix D). This list is derived from Part D claims data. The drugs identified will be expanded to the class level and used in the formulary review process. CMS understands that sponsors will not provide identical coverage of these drug classes, and CMS' review will focus on ensuring that sponsors present a balanced formulary. These drug classes will cover common diseases and conditions, and will allow CMS to ensure that sponsors are covering the most widely used medications, or therapeutically similar medications, for the most common conditions.

- CMS will review all Part D sponsors' formularies to ensure they contain all commercially available vaccines (unless excluded due to available reimbursement under Part B, e.g., influenza or pneumococcal vaccines, *or if a commercially available vaccine manufacturer does not participate in the coverage gap discount program*). Sponsors will only be allowed to use drug utilization management tools to:
 - Assess the necessity of vaccines that are less commonly administered in the Medicare population, such as anthrax and yellow fever vaccines;
 - Facilitate use of vaccines in line with Advisory Committee on Immunization Practices (ACIP) recommendations; and
 - Evaluate potential reimbursement of those vaccines that could be covered under Part B when directly related to the treatment of an injury or direct exposure to a disease or condition (e.g., tetanus).
- *UM restrictions will also be evaluated as part of the formulary content review. In addition to ensuring that the use of these tools are consistent with industry best practices, CMS will also compare all sponsors' formulary submissions to analyze the comparative use of UM tools. When outliers are identified, CMS will request a clinical justification that supports the use of the submitted edits.*

All formularies will be evaluated using the criteria above in this section. Outliers for each area of review will be further evaluated by CMS to determine whether the outlier is deemed potentially discriminatory. Examples of this may include a lack of appropriate drug classes to treat certain diseases, a lack of sufficient drugs in a therapeutic class, inappropriate tier placement that would discriminate against a group of beneficiaries, or missing drugs that *could discourage certain types of beneficiaries from enrolling in the plan*. If any of the outliers appear to create problems of access, sponsors will have the opportunity to present reasonable clinical justifications.

30.2.8 - Formulary Submission Timeline

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors that fail to meet formulary submission and re-submission deadlines during the formulary approval process may face a CMS determination that CMS cannot approve their Part D bids. For most Part D sponsors, a failure to obtain bid approvals will result in the termination of their Part D sponsor or MA organization contracts effective at the end of the existing contract year. In the case of an initial Part D sponsor or MA organization contract applicant, CMS would decline to enter into a contract with the organization.

Such a determination would be made on the basis that the organization had failed to submit a bid which CMS could approve, a determination that would not be subject to a request for appeal under Subpart N of 42 CFR §423 (for Part D sponsors) and 42 CFR §422 (for MA organizations).

30.3 - Formulary Changes

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

The removal of any drug, whether a Part D drug or a supplemental drug offered as a supplemental benefit under an enhanced alternative benefit design, is subject to the formulary change guidance contained in the following sections.

30.3.1 - Limitation on Changes in Therapeutic Classification

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change formulary categories and classes after the last CMS specified HPMS formulary upload date for the upcoming contract year.

30.3.2 - Limitation of Formulary Changes Prior to Beginning of Contract Year

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Except when the *FDA* deems a Part D drug unsafe or a manufacturer removes a Part D drug from the market, a Part D sponsor may not remove a covered Part D drug from its formulary, or make any change in preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in section 42 CFR [§423.38\(b\)](#) and 60 days after the beginning of the contract year associated with the annual coordinated election period.

30.3.3 - Midyear Formulary Changes

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the contract year. CMS believes that formulary stability is extremely important so that enrollees maintain access to the benefit they chose during enrollment as represented to them by the sponsor. However, prescription drug therapies are constantly evolving, and new drug availability, medical knowledge, and opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur over the course of the year. As recognized in the statute and regulations, these new developments may require formulary changes during the year in order to provide high-quality, low-cost prescription drug coverage.

30.3.3.1 - Policy Regarding Formulary Changes

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

The following is CMS' policy regarding formulary changes:

- Part D sponsors may expand formularies by adding drugs to their formularies, reducing copayments or coinsurance by placing a drug on a lower cost-sharing tier, or deleting

utilization management requirements at any time during the year. *Such changes can be implemented immediately by a sponsor and should be submitted to CMS at the next scheduled opportunity.*

- *CMS considers negative formulary changes to include the following: 1) removal of a drug from a formulary; 2) increasing the cost-sharing status of a drug on the formulary subsequent to a change in tier; 3) adding, or making more restrictive: a) prior authorization requirements, b) quantity limits, c) step therapy requirements, and 4) imposing other restrictions on a drug that require CMS approval.*

CMS also considers the expiration of an approved exception to be a negative formulary change for purposes of required advance notice to the beneficiary. Sponsors should consult chapter 18, section 30.2 for further guidance on beneficiary notification requirements for approved exceptions, available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip>.

- *Formulary Maintenance Changes: After March 1, Part D sponsors may make maintenance changes to their formulary, such as replacing brand name with new generic drugs or modifying formularies as a result of new information on drug safety or effectiveness.*
- *Non-maintenance (Other) Formulary Changes: Part D sponsors may remove Part D drugs from their formulary, move covered Part D drugs to a less preferred tier status, or add utilization management requirements. For these additional types of formulary changes approved by CMS, Part D sponsors should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the contract year.*

Part D sponsors must receive CMS approval of any changes to their formulary; however, Part D sponsors are not required to obtain CMS approval for drugs that have been withdrawn from the market by either the FDA or a product manufacturer.

Beginning in CY 2014, while CMS will continue to offer a summer formulary update, formulary changes during this particular update submission will be limited to: 1) the addition of drugs that are new to the summer release of the Formulary Reference File (historically posted in July); and 2) the submission of negative changes on brand name drugs, only if the equivalent generic is added to the summer FRF and corresponding formulary file. As noted previously, positive formulary changes can be implemented at any time, consistent with guidance on the timely ongoing review of all new FDA-approved drug products and indications.

Sponsors should consult the Prescription Drug Benefit Manual, Chapter 2 (Medicare Marketing Guidelines), Section 60.5, “Formulary and Formulary Change Notice Requirements”, and Chapter 5 for further guidance related to print and website versions of their formularies.

30.3.3.2 - Formulary Maintenance Changes

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

In order to promote best practices and protect the interests of Medicare beneficiaries, CMS will generally give positive consideration to the following types of formulary changes:

- Removal or placement in a less preferred tier of a brand name drug upon the availability and addition of an A-rated generic or multi-source brand name equivalent, at a tier *with lower* cost to the beneficiary.
- Removal of a non-Part D drug inadvertently included on the formulary.
- Addition of utilization management tools based upon a new FDA *boxed* warning.
- Removal of a drug based upon a new FDA market withdrawal notice.
- Removal of a drug based on long term shortage and market availability (described in chapter 5, section 50.13).
- Removal or placement in a less preferred tier based upon new clinical guidelines or information recognized by CMS (e.g., CDC's recommendation against using older antivirals for treatment and prophylaxis of the flu).
- The addition of utilization management when necessary to effectuate other approved formulary changes (e.g., prior authorization on a brand name drug when generic is now available on formulary at a lower cost), to help determine B vs. D coverage (subject to CMS guidance on least burdensome ways to make this determination), or to promote safe utilization of a Part D drug based upon new clinical guidelines or information.

Part D sponsors will need to provide a justification when submitting formulary maintenance change requests, but they may assume that change requests based upon these justifications are approved if they do not hear from CMS within 30 days of submission.

30.3.3.3 - Non-maintenance (Other) Formulary Changes (Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Experience with formulary management indicates that the vast majority of formulary changes are “maintenance” changes that would generally be approved by CMS. CMS will review additional types of non-maintenance formulary change requests and their corresponding justification. Part D sponsors should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the contract year. These additional types of change requests include, but are not limited to:

- Changing preferred or non-preferred formulary drugs, adding utilization management, or increasing cost sharing on preferred drugs (unrelated to the reasons stated above);
- Removing dosage forms; or

- Exchanging therapeutic alternatives (either by formulary addition/removal or tier exchanges).

If CMS disapproves a formulary change request, the justification for disapproval will generally be based on one of the following:

- The reasonableness and/or necessity for the proposed change in the context of preventing any appearance of “bait and switch” in the formulary. Medicare beneficiaries select Part D sponsors, in part, based on the formulary that is marketed during annual open enrollment and, therefore, have a legitimate expectation that they will have continuing access to coverage of the Part D drugs they are using throughout the contract year. This beneficiary expectation will be balanced against the sponsor’s desire to practice good formulary management in order to provide a low-cost, high-quality prescription drug benefit that continues to effectively meet the needs of beneficiaries. Part D sponsors may avoid any appearance of a “bait and switch” concern by exempting enrollees who are currently using the affected drugs from the formulary change for the remainder of the contract year.
- The proposed change on its face in the context of substantially discouraging enrollment by certain beneficiary groups.
- The impact of the proposed change on the formulary as a whole to ensure the formulary continues to satisfy the minimum formulary requirements established by CMS.

Because these additional types of change requests will require more extensive review by CMS, Part D sponsors must not implement such changes until they receive explicit notification of approval from CMS and must not issue any beneficiary notices of such forthcoming changes prior to receiving explicit and affirmative CMS approval.

30.3.4 - Provision of Notice Regarding Formulary Changes **(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)**

Part D sponsors must provide notice of formulary changes as outlined in the following sections. Additionally, for formulary maintenance changes (described in section 30.3.2), CMS will not require Part D sponsors to wait for approval before sending notice of a proposed formulary change to required parties. For these changes, a Part D sponsor may choose to provide notice to CMS and other required parties at the same time. Part D sponsors will provide notice to CMS via the HPMS system, which will also require plans to specify the intended effective date. Although sponsors may provide notice to all required parties prior to receiving CMS approval, sponsors might prefer to wait so that they do not risk sending notice of a change that is subsequently disapproved by CMS. For formulary non-maintenance or “other” changes (described in section 30.3.3.3), Part D sponsors must not issue any beneficiary notices until CMS has explicitly approved the non-maintenance change.

30.3.4.1 - Beneficiary Notice Requirements **(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)**

Prior to making any *negative formulary* change *during the contract year*, a Part D sponsor must either:

- Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or
- At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed and written notice of the formulary change.

If a beneficiary is not “affected” by a formulary change (in other words, exempted from a formulary change), notice is not required.

The written notice must contain the following information:

- The name of the affected covered Part D drug;
- Whether the Part D sponsor is removing the covered Part D drug or changing its preferred or tiered cost-sharing status;
- The reason why the Part D sponsor is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;
- Alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and
- The means by which enrollees may obtain a coverage determination under 42 CFR [§423.566](#) or exception under 42 CFR [§423.578](#).

As an alternative to providing written notice, Part D sponsors may provide such notice electronically if, and only if, an enrollee affirmatively elects to receive such notice electronically.

30.3.4.2 - Notice for Other Entities

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Prior to making any *negative formulary* change *during the contract year*, a Part D sponsor must provide at least 60 days’ notice to CMS, State Pharmaceutical Assistance Programs (as defined in 42 CFR [§423.454](#)), entities providing other prescription drug coverage (as described in 42 CFR [§423.464](#)(f)(1), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective.

To the extent possible, sponsors may elect to provide State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage (as described in 42 CFR [§423.464](#)(f)(1), authorized prescribers, network pharmacies, and pharmacists an annual notice providing information on the sponsor’s formulary change policy (i.e., length of notice, methods of

communication with beneficiaries, and any electronic notices providers may receive at the point-of-sale regarding formulary status) and the sponsor's Web site where these entities can verify the formulary status of particular drugs.

30.3.4.3 - Provision of Notice Regarding Formulary Changes *Subsequent to Removal from the Market* *(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)*

Part D sponsors may immediately remove from their formularies covered Part D drugs deemed unsafe by the *FDA* or removed from the market by their manufacturer without meeting the advance notice requirements specified in this section. However, Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in 42 CFR §423.454), entities providing other prescription drug coverage (as described in 42 CFR §423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements set forth in this section. CMS expects that this retrospective notice will occur as soon as possible to inform enrolled beneficiaries of potential safety concerns surrounding medications they are taking, especially those beneficiaries who may have a 90 day supply and will not interact with the pharmacy for an extended period.

In instances where there has been an announcement of a market withdrawal, but the withdrawal has not yet taken place, Part D sponsors may opt to either remove the drug immediately with a retrospective notice to "affected enrollees" or provide an advance notice. CMS expects Part D sponsors to consider all pertinent information available from the FDA related to the withdrawal.

30.3.4.4 - Notice Requirements for Pending Formulary Changes **(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)**

When a Part D sponsor notifies CMS of a formulary change in HPMS, the change is assigned a prospective effective date. During the period of time between when a Part D sponsor has notified CMS of a prospective change and the actual effective date of that change, Part D sponsors must ensure appropriate beneficiary protections are implemented should a beneficiary who has not been notified of the change present with a new prescription for the drug whose formulary status is changing.

For maintenance changes outlined in section 30.3.3.2, the Part D sponsor must implement the beneficiary notice requirements contained in section 30.3.4.1 (i.e., 60 days of advance written notice before implementing the change for the individual). For example, assume on March 1st, a Part D sponsor notifies CMS via HPMS that it is removing a brand name drug from its formulary due to the availability of a new generic. The sponsor indicates the effective date for this formulary change will be May 1st. If a beneficiary were to present on April 1st with a new prescription for the brand name drug pending removal, the Part D sponsor would provide written notice of the change and not implement the change until June 1st, in order to provide the full 60 days of advance notice to that beneficiary.

A Part D sponsor may elect to provide written notice to all of its enrollees of a pending formulary maintenance change in lieu of notifying only the “affected enrollees.” Such an approach would satisfy the beneficiary notice requirements in section 30.3.4.1 because all enrollees, including “affected enrollees” would receive advance notice of a formulary change. In addition, it would preclude the plan from needing to extend the formulary change effective date for those enrollees who present with a new prescription for the drug between the date when a Part D sponsor notifies CMS of a prospective change and the actual effective date of that change. However, Part D sponsors are still required to provide advance written notice of a formulary change and a 60 day-supply of the drug whose formulary status is changing to those beneficiaries who enroll in the plan after the initial advance formulary change notice, as described above.

For non-maintenance changes outlined in section 30.3.3.3, the Part D sponsors must not implement the formulary change for a beneficiary who presents with a new prescription for a pending formulary drug. In accordance with our non-maintenance formulary change policy, enrollees currently taking the affected drug must be exempt from the formulary change for the remainder of the contract year. For example, assume on March 1st, a Part D sponsor notifies CMS via HPMS it is removing a drug from its formulary with no replacement. CMS approves the change. The sponsor indicates the effective date for this formulary change will be May 1st. If a beneficiary were to present on April 1st with a new prescription for the drug pending removal, the Part D sponsor would not implement this change for the beneficiary for the remainder of the contract year.

30.3.5 - Formulary Change Notice in Advance of Upcoming Contract Year *(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)*

Enrollees must receive an annual notice of change (ANOC) by *September 30th* prior to the upcoming contract year. The ANOC is intended to outline benefit changes for the upcoming year including changes in cost-sharing and drug tier structures. Because the upcoming year’s formulary is viewed as a new formulary, Part D sponsors are not required to identify specific drug changes impacting enrollees in their explanation of benefits, or provide a 60-day notice of changes for the upcoming year’s formulary. However, enrollees must receive a comprehensive or abridged formulary with the ANOC, which will provide enrollees with at least *90* days to review the new formulary to determine if their medications are covered and whether the cost-sharing for their covered medications will change in the upcoming contract year.

30.4 - Transition

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

A Part D sponsor must provide for an appropriate transition process for *certain* enrollees *who are* prescribed Part D drugs *that represent ongoing therapy with that drug, but* that are *non-*formulary. *The purpose of providing a transition supply is to promote continuity of care and avoid interruptions in drug therapy while a switch to a therapeutically equivalent drug or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons can be effectuated.* The transition policy must satisfy the requirements in the following sections.

For the purposes of transition requirements in section 30.4, CMS defines non-formulary Part D drugs to mean: (1) Part D drugs that are not on a sponsor's formulary, (2) drugs previously approved for coverage under an exception once the exception expires, and (3) Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose, under a plan's utilization management requirements. This is because a formulary drug whose access is restricted via UM requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant UM requirements are not met for a particular enrollee. However, if the plan's QL is equal to an FDA maximum dose limit, plans do not have to allow doses greater than this limit as part of a transition supply.

30.4.1 - Transition Requirements

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

A Part D sponsor's transition process is necessary with respect to the transition of: (1) new enrollees into prescription drug plans following the annual coordinated election period; (2) newly eligible Medicare beneficiaries from other coverage; (3) *enrollees* who switch from one plan to another after the start of the contract year; (4) *current enrollees affected by negative formulary changes (as defined in section 30.3.3.1) across contract years; and (5) enrollees residing in LTC facilities (see section 30.4.6). See Appendix E for a listing of multiple scenarios when beneficiaries may be eligible for a transition fill under this guidance.*

A Part D sponsor's transition process must address situations in which an individual first presents at a *network* pharmacy with a prescription for a drug that is *non-formulary, and should be presumed to be* unaware of what is covered by the plan or of the sponsor's exceptions process for providing access to Part D drugs that are not covered.

A beneficiary's transition period begins with the date of each enrollment. CMS receives frequent questions about who constitutes a "new" enrollee, and who constitutes a current enrollee affected by negative formulary changes, who are entitled to a transition fill. CMS believes these questions should first be considered in the context of the purpose of the transition policy. The purpose of the transition policy is to address situations when an enrollee's ongoing drug therapy (whether the Part D sponsor is able to actually ascertain ongoing therapy or not) could be potentially interrupted by a drug being non-formulary. Thus, an enrollee who stays with the same contract number but changes PBPs is potentially entitled to a transition fill because the enrollee could experience a negative formulary change. However, just because a member's drug therapy could potentially be interrupted does not mean that the member will necessarily receive a transition fill. In this example, for instance, the formulary may not have changed (which means there have also been no addition of utilization management edits). Also, in some cases, the sponsor may have the claims history for the member from the just prior PBP, and thus, the sponsor may be able to determine that the member is not taking a non-formulary medication. In other words, the sponsor may be able to determine at the POS that there will be no interruption in medication therapy for the member, and therefore the member is not eligible for a transition fill.

30.4.2 - General Transition Process

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors must ensure that they have provided their enrollees who have used a transition benefit with the appropriate assistance and information necessary to enable them to better understand the purpose of the transition. Steps that sponsors should consider to ensure a meaningful transition include:

- Analyzing claims data to determine which enrollees require information about their transition supply.
- Contacting those enrollees to ensure they have the necessary information to enable them to switch to a formulary product or as an alternative to pursue necessary prior authorizations or formulary exceptions.
- Increasing call center capacity, including pharmacy help lines, to respond to an anticipated increase in call volume from affected enrollees regarding the sponsor's transition process.
- Making arrangements to continue to provide necessary drugs to an enrollee by extending the transition period, on a case-by-case basis, if the enrollee's exception request or appeal has not been processed by the end of the minimum transition period.

30.4.3 - New Prescriptions Versus Ongoing Drug Therapy

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

CMS is aware that it may be difficult for Part D sponsors to distinguish between new prescriptions for non-formulary Part D drugs and refills for ongoing drug therapy involving non-formulary Part D drugs. *CMS believes a minimum of a 108 day look-back (consistent with other reviews) is typically needed to adequately document ongoing drug therapy.* Although Part D sponsors *may be able to access prior drug claims history for an enrollee of an affiliated plan,* or may attempt to follow up with prescribing physicians and pharmacies to ascertain the status of a prescription presented during the transition period, CMS clarifies that if a sponsor is unable to make this distinction at the point of sale, *the sponsor is* required to *provide the enrollee with a transition fill.* In other words, *for transition purposes,* a brand-new prescription for a non-formulary drug will not be treated any differently than an ongoing prescription for a non-formulary drug when a distinction cannot be made at the point of sale.

Generally, a sponsor may apply any CMS approved PA or ST after the transition fill has been satisfied if the sponsor determines that the transition fill was the first fill. However, for protected class drugs that are subject to PA or ST on new starts only, in accordance with section 30.2.5, if a sponsor allows an initial fill because it cannot determine at the point of sale that an enrollee is not currently taking the protected class drug (during transition or otherwise), the sponsor shall treat such enrollees as currently taking the drug. Therefore, any protected class PA or ST requirements for new starts are no longer applicable after the first fill has been provided.

30.4.4 - Transition Timeframes and *Transition Supply* *(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)*

Within the first 90 days of coverage under a new plan, plans must provide a *transition supply* when the beneficiary requests a non-formulary drug. This 90 day timeframe applies to retail, home infusion, long-term care, and mail-order pharmacies. CMS believes it makes sense to both limit and define the amount of time during which a transition process is applicable. Thus, plans *are* required to provide a temporary fill anytime during the first 90 days of a beneficiary's enrollment in a plan. *However*, since certain enrollees may join a plan at any time during the year, this requirement *applies* beginning on *such* an enrollee's first effective date of coverage *instead of* to the first 90 days of the *plan* year. *If an enrollee leaves a plan and re-enrolls during the original 90 day transition period, the transition period begins again with the new effective date of enrollment, because it is possible that the enrollee's drug therapy changed while the enrollee was not with the plan and that therapy could be potentially interrupted. However, if there is no gap in coverage, there is no new transition period.*

30.4.4.1 - Timeframe and *Transition Supply* in the *Retail* Setting *(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)*

In the *retail* setting, the *transition fill* of non-formulary Part D drugs must be for at least 30 days, unless the prescription is written by a prescriber for less than 30 days. Part D sponsors *must allow multiple fills to provide at least 30 days of medication in accordance with 42 CFR §423.120(b)(3)(iii)(A).* *If the smallest available marketed package size exceeds a 30 day supply, the sponsor must still provide a transition supply when required. Part D sponsors and their processors must determine how to process claims in such cases.*

30.4.4.2 - Timeframe and *Transition Supply* in the Long Term Care Setting *(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)*

The *transition supply* of non-formulary Part D drugs for a new enrollee in an LTC facility *must* be for *at least 91 days, and may be up to at least 98 days to be consistent with the applicable dispensing increment in the LTC setting (unless a lesser amount is actually prescribed by the prescriber).* *Part D sponsors must allow multiple fills if needed to provide the full amount of medication prescribed, in accordance with 42 CFR §423.120(b)(3)(iii)(B).* *If the smallest available marketed package sizes do not align with this timeframe, the sponsor must still provide a transition supply when required. Part D sponsors and their processors must determine how to process claims in such cases.* CMS is requiring up to a 91- to 98-day transition supply given that many LTC pharmacies and facilities *must* dispense *brand name* medications in *14-day or less* increments. *Also*, sponsors must honor multiple fills of non-formulary Part D drugs as necessary during the entire length of the transition period.

CMS is permitting Part D sponsors the option of sending required transition fill notices to network long term care pharmacies. In sending enrollees residing in LTC facilities a model transition notice via U.S. mail within 3 business days *of adjudication* of the transition fill, Part D sponsors may *instead* elect to send the beneficiary transition notice to the LTC pharmacy serving

the beneficiary's LTC facility. The LTC pharmacy must then ensure delivery of the notice to the beneficiary within 3 business days *of adjudication* of the fill.

Part D sponsors electing this option must update their existing transition policy to specifically address that:

1. The sponsor maintains documentation of the LTC pharmacies' willingness to be delegated transition notice responsibilities; and
2. The sponsor maintains a fully functional electronic communication process with the LTC pharmacy once a transition fill has occurred (within 3 business days).
3. The LTC pharmacy will maintain a process that demonstrates notice has been provided to the beneficiary (or his/her representative) within the 3-day period.

This option must be in place prior to the start of the contract year; otherwise, the Part D sponsor must continue to provide notice directly to the beneficiary (or his/her designated representative) via U.S. mail.

30.4.4.3 - Transition Extension

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor may need to make arrangements to continue to provide necessary drugs to an enrollee via an extension of the transition period, on a case-by-case basis, to the extent that his or her exception request or appeal has not been processed by the end of the minimum transition period. It is vital that sponsors give affected enrollees clear guidance regarding how to proceed after a temporary fill is provided, so that an appropriate and meaningful transition can be effectuated by the end of the transition period. Until that transition is actually made, however, either through a switch to an appropriate formulary drug, or a decision is made regarding an exception request, continuation of drug coverage is necessary, other than for drugs not covered under Part D.

30.4.5 - Transition Across Contract Years

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

After enrollees receive their ANOC *in* a given year, CMS expects sponsors to select *at least* one of the following two options for effectuating an appropriate and meaningful transition for enrollees whose drugs *will be affected by negative formulary changes in the upcoming year*:

- Provide a transition process for current enrollees *at the start of the new contract year*. In order to prevent coverage gaps, sponsors choosing this option are expected to provide a *transition* supply of the requested prescription drug *beginning January 1* and provide enrollees with *the required transition* notice; or
- Effectuate a transition for current enrollees prior to the start of the new contract year. In effectuating this transition, sponsors must aggressively work to (1) prospectively

transition current enrollees to a therapeutically equivalent formulary alternative; and (2) *adjudicate any* requests *received* for exceptions to the new formulary prior to the start of the contract year (*consistent with chapter 18, section 30.2.2, available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip>*). *However, if* sponsors have not successfully transitioned affected enrollees to a therapeutically equivalent formulary alternative or *adjudicated* an exception request *prior to* January 1, they will be expected to provide a transition supply beginning January 1 and *the required transition notice*. *If a sponsor approves an exception request pursuant to this section, the sponsor must authorize payment prior to January 1 of the new contract year.*

Current Enrollees - Part D sponsors that can identify objective information demonstrating that a meaningful transition has occurred (such as the *adjudication* of an exception request and/or evidence of a new prescription claim for a formulary alternative *paid by the sponsor prior to the start of the new contract year*) do not have to provide a transition supply in the new contract year for that beneficiary *as the next fill would either be a covered fill of the medication approved under the exception process or a covered fill of the formulary alternative that the enrollee transitioned to before the start of the new contract year*. However, lacking such *documentation*, the sponsor is expected to provide a transition supply in the new contract year and provide the corresponding transition notice.

New Enrollees - Part D sponsors must extend their transition policies across contract years should a beneficiary enroll into a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. For example, if a beneficiary enrolls effective December 1, in a plan whose transition policy affords a 90-day transition period for LTC enrollees and that beneficiary requires a transition supply in mid-December, the sponsor must offer a full 90-day transition period beginning December 1 and extending into the following contract year. In addition, sponsors must send beneficiaries with a November 1 or December 1 effective enrollment date an ANOC as soon as practicable after the effective enrollment date. This ANOC will *still* serve as advance notice of any formulary or benefit changes in the following contract year.

30.4.6 - Emergency Supply for Current Enrollees *in the LTC Setting* ***(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)***

Since, as a matter of general practice, LTC facility residents must receive their medications as ordered without delay, Part D sponsors must *also* cover emergency *supplies* of non-formulary Part D drugs for LTC facility residents *after the transition period*.

During the first 90 days after enrollment, *the enrollee* will receive a transition supply *as described in section 30.4*. However, to the extent that an enrollee in an LTC setting is outside his or her 90-day transition period, the sponsor must still provide an emergency supply of non-formulary Part D drugs while an exception or prior authorization *request is being processed*. These emergency supplies of non-formulary Part D drugs must be for at least 31 days of medication, *regardless of dispensing increments*, unless the prescription is written by a prescriber for less than 31 days. *In cases where the smallest available marketed package size is*

not available for less than a 31-day supply, the sponsor must still provide an emergency supply when required. Part D sponsors and their processors must determine how best to process claims in such cases. Multiple 14-day or less supplies can be supplied for brand name drugs to meet a minimum of a 31-day emergency supply requirement. A sponsor is not expected to provide more than a one-time 31-day emergency fill of a particular drug per LTC stay.

30.4.7 - Level of Care Changes

(Rev. 10, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

In addition to circumstances impacting new enrollees who may enter a plan with a medication list that contains non-formulary Part D drugs, other circumstances exist in which unplanned transitions for current enrollees could arise and in which prescribed drug regimens may not be on sponsor formularies. These circumstances usually involve level of care changes in which a beneficiary is changing from one treatment setting to another. For example, beneficiaries who enter LTC facilities from hospitals are sometimes accompanied by a discharge list of medications from the hospital formulary with very short term planning taken into account (often under 8 hours). Similar situations may exist, for example, for beneficiaries who are discharged from a hospital to a home; for beneficiaries who end their skilled nursing facility Medicare Part A stay (where payments include all pharmacy charges) and who need to revert to their Part D plan formulary; for beneficiaries who give up hospice status to revert to standard Medicare Part A and B benefits; for beneficiaries who end an LTC facility stay and return to the community; and for beneficiaries who are discharged from psychiatric hospitals with drug regimens that are highly individualized.

For these unplanned transitions, beneficiaries and providers must clearly avail themselves of sponsor exceptions and appeals processes. CMS has streamlined the grievance, coverage determination, and appeals process requirements in order to ensure that beneficiaries receive quick determinations regarding the medications they need. In all cases, CMS makes it clear that a Part D sponsor is required to make coverage determinations and redeterminations as expeditiously as the enrollee's health condition requires.

Effective transition of care at time of discharge to home is a major concern in LTC. Ensuring appropriate medication reconciliation in the community is a safety issue, and requires pre-discharge planning. This optimally involves prescriptions being written and transmitted to the patients' families in the week before discharge, to assure that the medications are obtained in advance of community discharge, to prevent a gap in care. The billing date may appear to overlap the skilled nursing home stay, but the medications, which may be dispensed by either the LTC or a retail pharmacy, are to be used in the home setting. While Part A does provide reimbursement for "a limited supply" to facilitate beneficiary discharge, beneficiaries must be permitted to have a full outpatient supply available to continue therapy once this limited supply is exhausted. This is particularly true for beneficiaries using mail-order pharmacy, home infusion therapy, or residing in rural areas where obtaining a continuing supply of drugs may involve certain delays. The current standard of care promotes caregivers receiving outpatient Part D prescriptions in advance of discharge from a Part A stay.

When an enrollee is admitted to or discharged from an LTC facility, he or she will not have access to the remainder of the previously dispensed prescription (through no fault of his or her own) and, therefore, sponsors must allow the enrollee to access a refill upon admission or discharge. An early refill edit is a utilization management tool used to promote compliance and to prevent waste. An early refill edit cannot be used to limit appropriate and necessary access to an enrollee's Part D benefit. For example, if a patient gets a prescription for 30 tablets for a 30 day supply (i.e., 1 tablet daily), but the prescriber changes the dose to 2 tablets daily after only 10 days, it would be inappropriate for a sponsor to deny as "too soon" a claim for a new prescription with the new dosage because the enrollee will not have enough medication to last until the originally scheduled refill date.

However, even with these protections, there may exist some period of time in which beneficiaries with level of care changes have a temporary gap in coverage while an exception is processed. For this reason, CMS strongly encourages Part D sponsors to incorporate processes in their transition plans that allow for transition supplies to be provided to current enrollees with level of care changes.

30.4.8 - Edits for Transition Fills

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

A Part D sponsor must ensure that an enrollee is able to *obtain* a temporary supply of non-formulary Part D drugs *from a network pharmacy* without unnecessary delays *in accordance with section 30.4*. Part D sponsors may only apply certain drug utilization management edits during a beneficiary's transition period. Drug utilization management edits that are appropriate during a beneficiary's transition period include the following:

- Edits to help determine Part *A or B* vs. Part D coverage (*see section 20.2*);
- Edits to prevent coverage of non-Part D drugs (e.g., excluded drugs *such as a drug that may be used for sexual dysfunction, or formulary drugs being dispensed for an indication that is not medically accepted*) (*see sections 10.6 and 20*); and
- Edits to promote safe utilization of a Part D drug (e.g., *a beneficiary-level opioid claim edit*; quantity limits based on FDA maximum recommended daily dose *such as APAP*; early refill edits) (*see section 30.2.2.2*).

CMS notes that although Part D sponsors may implement quantity limits that are based on approved product labeling during a beneficiary's transition period, to the extent that the prescription is dispensed for less than the written amount due to a plan edit, sponsors must *still* provide refills *to meet the* transition supply *requirement*. For example, if a beneficiary presents at a retail pharmacy with a prescription for 1 tablet per day for 30 days and a plan has a quantity limit edit in place that limits the days' supply to 14 per prescription for safety purposes, the beneficiary would receive a 14-day supply (consistent with the safety edit). At the conclusion of the 14-day supply, the beneficiary should be entitled to another *16*-day supply while he/she continues to pursue an exception with the Part D plan, or a switch to a therapeutic alternative that is on the plan's formulary.

Irrespective of transition, all of these edits are subject to exceptions and appeals. For example, if a quantity limit *safety* edit (based on *an FDA* maximum recommended daily dose) results in the dispensing of a quantity that is less than indicated on the prescription and is less than the plan allowable days' supply (as determined by the prescribed daily dose), Part D sponsors must ensure that beneficiaries are made aware of this quantity limit and that an exception is required to obtain a greater quantity. Part D sponsors must expeditiously process such exception requests so that beneficiaries will not experience unintended interruptions in medically necessary Part D drug therapies and/or will not inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.

Beneficiary-level opioid point-of-sale claim edits (and cumulative opioid MED edits, as noted in the guidance on safety edits in section 30.2.2.2) may be applied during transition.

- *If a beneficiary level point-of-sale opioid claim edit has been implemented, CMS expects the beneficiary to only be able to receive during a transition period the opioid dosage that has been determined to be medically necessary and appropriate, based upon the case management process. In other words, if a sponsor currently has a beneficiary-level opioid claim edit in place in one of its Part D plans and the beneficiary enrolls in another one of the sponsor's plans, or the sponsor has received information from the prior plan from which the beneficiary disenrolled and the sponsor is satisfied that the edit should be continued, the sponsor may apply the edit during transition.*

For new beneficiaries presenting with a prescription that represents ongoing therapy with a non-formulary opioid medication or a formulary opioid medication subject to PA or ST under the new plan's utilization management rules, a temporary supply can be provided during transition in accordance with this section, as long as the temporary transition fill does not exceed plan-level limits, cumulative opioid MED edits, or beneficiary-specific limits documented by the previous plan that the current plan also applied. For non-formulary medications, the safety and dosing should be considered as part of the coverage determination process when such determinations are requested.

30.4.9 - Cost-sharing Considerations

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Starting in 2015, a Part D sponsor must charge cost sharing for a temporary supply of drugs provided under its transition process such that the following conditions are met:

- *For LIS enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts.*
- *For non-LIS enrollees, a sponsor must charge—*

- *The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with §423.578(b); and*
- *The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.*

30.4.10 - Transition Notices

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

A successful transition process is contingent upon informing enrollees and their *health care provider* about their options for ensuring that enrollees' medical needs are safely accommodated within a Part D sponsor's formulary. An enrollee who receives a temporary supply of a non-formulary Part D drug at a network pharmacy might simply assume that, by virtue of filling his or her prescription, that the plan will cover that drug for the remainder of the contract year. For this reason, sponsors must provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules).

Part D sponsors will be required to send a written notice, via U.S. First Class mail, to each enrollee who receives a transition fill. This standard is consistent with CMS' requirement that other beneficiary communications, including formulary change notices and explanations of benefits, be sent via U.S. First Class mail. In addition, this notice must be sent to each affected enrollee within 3 business days *of adjudication* of the temporary *transition* fill. *If the enrollee completes his or her transition supply in several fills, the sponsor is required to send notice with the first transition fill only.* CMS believes this turnaround is necessary in order to provide an affected enrollee with sufficient time -- especially in light of CMS' 30-day transition fill policy in the *retail* setting -- to work with his or her prescriber to switch to a therapeutically equivalent drug that is on the plan's formulary or to process an exceptions request.

The notice must include the following elements:

- That the transition supply provided is temporary;
- That the enrollee should work with the sponsor as well as his or her health care provider to *satisfy utilization management requirements or to* identify appropriate therapeutic alternatives that are on the sponsor's formulary;
- That the member has the right to request a formulary exception, the timeframes for processing the exception, and the member's right to request an appeal if the sponsor issues an unfavorable decision; and
- The sponsor's procedures for requesting a formulary exception.

CMS provides Part D sponsors with a model *transition* letter. CMS expects that sponsors will make prior authorization or exception request forms available upon request to both enrollees and prescribing physicians and via a variety of mechanisms -- including by mail, fax, email, and on sponsor Web sites. To the extent that sponsors have the capacity, CMS encourages them to provide any prior authorization or exception request forms a beneficiary will need to effectuate a transition with the transition notice.

CMS strongly encourages point-of-sale notification *to* enrollees about transition supplies by pharmacists. CMS has worked with the pharmacy and drug benefit industry, including the National Council for Prescription Drug Programs (NCPDP), to incorporate a work-around process for using structured payment coding in the message field of billing transaction responses indicating that a particular fill is a transition supply. This process is consistent with the current NCPDP standard. For more information about Standardized Claims Messaging see chapter 14, section 50.5.

30.4.10.1 - Prescriber Notification of Transition Fills (Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors must ensure that their transition process includes reasonable efforts to notify prescribers of affected enrollees who receive a transition notice. CMS believes that prescriber notification is a means of further strengthening beneficiary protections when dealing with formulary changes or utilization management protocols for necessary medications, because the prescriber is in the best position to advise the beneficiary of the benefits or risks of switching to a different medication.

CMS believes either of the following examples constitutes a reasonable effort on the part of Part D sponsors to notify prescribers of affected enrollees who receive a transition notice. These examples are not exclusive examples of actions that may constitute reasonable efforts:

1) Providing a copy of the written transition notice labeled as the "PRESCRIBER COPY" directly to the prescriber of record. Adding this label to a copy of the transition notice does not require submission of the notice for review and approval by CMS. The copy may be provided to the prescriber via mail, fax, or electronic means.

2) Notifying the prescriber of record directly of the adjudication of the enrollee's transition fill via a phone call, or individualized or batch fax/electronic notification. This separate communication to the prescriber does not need to be submitted to CMS for review and approval.

CMS expects that plan sponsors will exercise due diligence in sending transition notices/communications to the prescriber of record's correct address, whether that entails acquiring contractor support to identify prescribers on Part D claims, contacting the network pharmacy for information on the prescription, or other means. However, CMS does not expect plan sponsors to verify that the prescriber has received a transition notice/communication. CMS also recognizes that notification of a prescriber who would be expected to have only a transient relationship with the beneficiary, such as a hospital-based physician, would generally not be useful.

30.4.11 - Public Notice of Transition Process

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors must make general information about their transition processes available to beneficiaries in a manner similar to information provided on formularies and benefit design. It is likely that individuals will base their decision on which prescription drug best meets their needs on a variety of factors. Having information about a sponsor's transition process in plan enrollment materials and Web sites, as well as on the Medicare Prescription Drug Plan Finder, may reassure beneficiaries that there will be procedures in place to assist them in switching to therapeutic alternatives or in obtaining a formulary exception where appropriate. It will also serve to educate advocates and other interested third parties – for example, State Medicaid agencies – about sponsor transition processes. CMS will make plan transition process information available via a required link from the Medicare Prescription Drug Plan Finder to individual sponsor Web sites.

30.5 - Provider and Patient Education

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary. See the marketing guidelines on CMS' Web site at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MMG_0511.pdf for more information on acceptable formulary marketing methods.

Chapter 6 - Appendix A
Common Acute Care Home Infusion Drugs

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

CMS is no longer maintaining this tool and has chosen to remove the table from Appendix A.

Chapter 6 – Appendix B

Part D Drugs/Part D Supplementary Drugs

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

This table provides Part D coverage clarifications for specific products/drugs/drug categories in accordance with statutory and regulatory requirements for Part D drugs. This is not an exhaustive list but only addresses those products/drugs/drug categories that have been the subject of frequently asked questions. Specific products not identified in this table should always be evaluated against the statutory and regulatory definition of a “Part D drug” before drawing conclusions from this table. This table does not address Part B versus Part D coverage questions.

Product/Drug/Drug Category (Listing is NOT all-inclusive)	May be covered under basic Part D benefit (when used for “medically accepted indication” ³ and not covered under Medicare Parts A or B)	Comments
Agents when used for anorexia, weight loss, or weight gain	No	Prescription drug products being used to treat AIDS wasting and cachexia are not considered agents used for weight gain or agents used for cosmetic purposes, and therefore such products are NOT excluded under such exclusion categories.
Agents when used for cosmetic purposes or hair growth	No	Treatments indicated for psoriasis, acne, rosacea, or vitiligo are NOT considered cosmetic.
Agents when used for symptomatic relief of cough and colds	No	Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and/or colds. For example, when “cough” medications are used <i>to treat a medical condition that causes a cough, such as the use of bronchodilators for the treatment of bronchospasm in asthma, CMS does not consider these “cough” medications as excluded drugs and, therefore, these medications may be</i>

³ Medically Accepted Indication for purposes of Part D is an FDA labeled indication or an indication supported by citation in either the American Hospital Formulary System (AHFS), or DRUGDEX®. *Exceptions may be possible when used as part of an anti-cancer chemotherapeutic regimen.*

Product/Drug/Drug Category (Listing is NOT all-inclusive)	May be covered under basic Part D benefit (when used for “medically accepted indication” ³ and not covered under Medicare Parts A or B)	Comments
		<i>covered under Part D. However, antitussives used to treat cough symptoms, and not the underlying medical condition causing the cough, are excluded from basic Part D coverage regardless of the medical condition causing the cough.</i>
Antihistamine/Decongestant Combinations (RX)	Yes, except when being used for symptomatic relief of cough and cold	
Barbiturates	<i>Yes</i>	<i>Covered for all medically accepted indications as of 2014</i>
Benzodiazepines	<i>Yes</i>	<i>Covered for all medically accepted indications as of 2013</i>
Blood glucose testing strips	No	NOT directly associated with injection of insulin
Electrolytes/Replenishers: *Potassium Sodium Calcium Magnesium	Yes	*Potassium Iodide products are excluded from Part D as Iodine products (minerals) because they are not used for potassium supplementation.
Erectile (ED) Dysfunction Drugs	No	Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the <i>FDA</i> . In addition, ED drugs will meet the definition of a Part D drug when prescribed for medically accepted indications approved by the FDA other than sexual or erectile dysfunction such as pulmonary hypertension. However, ED drugs will not meet the definition of a Part D drug when used off-label, even if the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act.
Extemporaneous Compounds, including sterile compounding of	Yes, but only costs for Part D drug components	Dispensing fee may include labor costs associated with mixing a compounded

Product/Drug/Drug Category (Listing is NOT all-inclusive)	May be covered under basic Part D benefit (when used for “medically accepted indication” ³ and not covered under Medicare Parts A or B)	Comments
IV’s and total parenteral nutrition	may be billed under Part D	drug product that contains at least one Part D drug component Part D drug components used solely as vehicles in a compound may be covered under Part D (e.g., D5W, Normal Saline)
Fioricet® (Bupropion, APAP, Caffeine)	Yes	See Commercially Available Combination Product Policy Section 10.3
Fioricet® with Codeine	Yes	See Commercially Available Combination Product Policy Section 10.3
Fiorinal® (Butalbital, ASA, Caffeine)	Yes	See Commercially Available Combination Product Policy Section 10.3
Fiorinal® with Codeine	Yes	See Commercially Available Combination Product Policy Section 10.3
Fosamax plus D	Yes	See Commercially Available Combination Product Policy Section 10.3
<i>Galzin</i>	No	
Heparin/Saline Flushes	No	See Section 10.6.
Injectable or IV Iron products such as Iron Dextran, Iron Sucrose and Sodium ferric gluconate	No	Prescription vitamin/mineral product
Insulin	Yes	
Insulin syringes	Yes	Covered <i>only</i> for injection of <i>insulin</i>
IV Solutions for hydration therapy	Yes	
Lancets	No	NOT directly associated with injection of insulin
Less-than-effective DESI Drugs (and those drugs identical, related or similar)	No	See Section 10.9
Leucovorin Calcium	Yes	
Librax®	No	Less-than-effective DESI drug

Product/Drug/Drug Category (Listing is NOT all-inclusive)	May be covered under basic Part D benefit (when used for “medically accepted indication” ³ and not covered under Medicare Parts A or B)	Comments
Limbital® (Amitriptyline/chlordiazepoxide)	Yes	See Commercially Available Combination Product Policy Section 10.3
<i>Lovaza®</i>	<i>Yes</i>	
<i>Medical foods</i>	<i>No</i>	<i>Defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act.</i>
Megestrol Acetate and Growth Hormone when used for AIDS wasting and cachexia	Yes	Prescription drug products that otherwise satisfy the definition of Part D drug are Part D drugs when used for AIDS wasting and cachexia if these conditions are "medically accepted" indications, as defined by section 1927(k)(6) of the Social Security Act (SSA), for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia as either agents used for weight gain or agents used for cosmetic purposes, and therefore such products cannot be excluded from the Medicare Prescription Drug Benefit by reference to section 1927(d)(2) of the SSA.
<i>Mephyton</i>	<i>No</i>	<i>Prescription vitamin/mineral product</i>
Methadone	Yes, except when indicated for the treatment of opioid dependence	A Part D drug is partially defined as “a drug that may be dispensed only upon a prescription”. . . . Consequently, Methadone is not a Part D drug when used for treatment of opioid dependence

Product/Drug/Drug Category (Listing is NOT all-inclusive)	May be covered under basic Part D benefit (when used for “medically accepted indication” ³ and not covered under Medicare Parts A or B)	Comments
		because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy.
Nonprescription/Over-the-counter (OTC) drugs ⁴	No, except insulin and supplies associated with the injection of insulin	Supplies associated with the injection of insulin include syringes, alcohol wipes, insulin pens and pen needles, gauze, and alcohol
PhosLo®	Yes	
<i>Phytonadione</i>	<i>No</i>	<i>Prescription vitamin/mineral product</i>
Polysaccharide Iron Complex	No	Prescription vitamin/mineral product
Prescription niacin products	Yes	Prescription niacin products are approved by the Food and Drug Administration as safe and effective drugs, are used therapeutically for the treatment of dyslipidemia, and do not serve as nutritional supplements or address a vitamin deficiency. These products are used at dosages much higher than appropriate for nutritional supplementation. For these reasons, CMS has concluded that these products should not be considered prescription vitamins for purposes of Part D coverage, and therefore, are not universally excluded from coverage under the Medicare prescription drug program.
Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations Examples: B vitamins (Folic Acid, Cyanocobalamin)	No	

⁴ Part D plans may include OTC drugs in step therapy protocols as part of their cost effective drug utilization management program. However, OTC drugs included in these step therapy protocols are considered administrative costs, not Part D drugs.

Product/Drug/Drug Category (Listing is NOT all-inclusive)	May be covered under basic Part D benefit (when used for “medically accepted indication”³ and not covered under Medicare Parts A or B)	Comments
Vitamin K (phytonadione) Vitamin D (ergocalciferol and cholecalciferol) Zinc (sulfate, acetate) Iron Iodine Multivitamin additives for parenteral nutrition		
Smoking cessation drugs (OTC)	No	
Smoking cessation drugs (RX)	Yes	
Sterile Saline/water for Irrigation	Yes	
Suboxone®, Subutex®	Yes	
Vitamin D Analogs (Calcitriol, doxercalciferol, <i>and</i> paricalcitol)	Yes	NOT considered prescription vitamins

Chapter 6 – Appendix C - Summary of Coverage Policy

MEDICARE PART B VERSUS PART D COVERAGE ISSUES

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

This document is not a statement or promise of coverage, but rather a high level summary of when something may be covered under Parts A, B or D, if all other coverage requirements are met. Appropriate coverage policies and guidance must be consulted for final coverage determinations.

Introduction

This document provides an overview of outpatient prescription drug coverage policies under Medicare. Beneficiaries who are inpatients of hospitals or skilled nursing facilities (SNF) during covered stays may receive drugs as part of their treatment. Typically, the payment for drugs is bundled into the Medicare Part A payments made to these types of facilities.⁵ Under the hospice benefit, beneficiaries receive drugs that are medically necessary for symptom control or for pain relief. In general, references are seen to five major categories of Medicare Part B drug spending: 1. drugs billed by physicians and typically provided in physicians' offices (such as chemotherapy drugs); 2. drugs billed by pharmacy suppliers and administered through durable medical equipment (DME), such as respiratory drugs given through a nebulizer; 3. drugs billed by pharmacy suppliers and self-administered by the patient (such as immunosuppressive drugs and some oral anti-cancer drugs); 4. separately billable drugs provided in hospital outpatient departments; and 5. separately billable End Stage Renal Disease (ESRD) drugs such as erythropoietin (EPO). Regional differences in Part B coverage policies for drugs can occur in the absence of a national coverage decision. A drug for which coverage is available under Part A or Part B, as it is being "prescribed and dispensed or administered" with respect to the individual, is excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage.

Medicare Part A and Part B Covered Drugs

Part A/B Covered Drugs Set by Statute

Traditional Medicare (Part A/B) does not cover most outpatient prescription drugs. Medicare bundled payments made to hospitals and skilled nursing facilities generally cover all drugs provided during a stay. Medicare also makes payments to physicians for drug or biological *products* that are not usually self-administered. This means that coverage is usually limited to

⁵ If these drugs are provided as part of a Medicare Part A covered inpatient hospital or skilled nursing facility stay, they are generally bundled in the Medicare Part A payment to the facility. The exception with regard to inpatient hospital services is clotting factor which is paid separately. For covered SNF stays certain high cost chemotherapy drugs are billed separately along with preventive injections (e.g. flu shots). If a beneficiary does not have Part A coverage, if Part A coverage for the stay has run out or if a stay is non-covered, hospitals and SNFs can be paid for most categories of Part B covered drugs.

drugs or biological *products* administered by infusion or injection. However, if the injection is generally self-administered (e.g., Imitrex), it is not covered.

Despite the general limitation on coverage for outpatient drugs under Part B, the law specifically authorizes coverage for the following:

- Durable Medical Equipment (DME) Supply Drugs. These are drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, external or implantable pump). The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. The largest Medicare expenditures for drugs furnished as a DME supply are for inhalation drugs, which are administered in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide). The other category of drugs Medicare covers as a DME supply are drugs for which administration with an infusion pump in the home is medically necessary (e.g. some chemotherapeutic agents).
- Immunosuppressive Drugs. Drugs used in immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a Medicare covered organ transplant.
- Hemophilia clotting factors. Hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors.
- Oral Anti-Cancer Drugs. Drugs taken orally during cancer chemotherapy provided they have the same active ingredients and are used for the same indications as chemotherapy drugs that would be covered if they were not self-administered and were administered as incident to a physician's professional service.
- Oral Anti-emetic Drugs. Oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen as a full therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration.
- Pneumococcal vaccine. The vaccine and its administration to a beneficiary if ordered by a physician.
- Hepatitis B vaccine. The vaccine and its administration to a beneficiary who is at high or intermediate risk of contracting hepatitis B.⁶

⁶ High risk groups currently identified include: individuals with ESRD; individuals with hemophilia who received Factor VIII or IX concentrates; clients of institutions for individuals for the mentally handicapped; persons who live in the same household as a hepatitis B Virus (HBV) carrier; homosexual men; illicit injectable drug abusers. Intermediate risk groups include: staff in institutions for the mentally handicapped and workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

- Influenza vaccine. The vaccine and its administration when furnished in compliance with any applicable state law. The beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.
- Antigens. These are prepared by a physician (usually an allergist) for a specific patient. The physician or physician's nurse generally administers them in the physician's office. In some cases the physician prepares antigens and furnishes them to a patient who has been taught to self-administer them at home.
- Erythropoietin (EPO). EPO for the treatment of anemia for persons with chronic renal failure who are on dialysis.
- Parenteral Nutrition. Parenteral nutrients are covered under the prosthetic benefit. They are available to beneficiaries who cannot absorb nutrition through their intestinal tract. Parenteral nutrition is administered intravenously and is regulated as a drug by the FDA.
- Intravenous Immune Globulin Provide in the Home. The Medicare Modernization Act created a benefit for the provision of intravenous immune globulin (IVIG) for beneficiaries with a diagnosis of primary immune deficiency disease. Coverage is provided if a physician determines that the administration of IVIG in the patient's home is medically appropriate. Payment is limited to that for the IVIG itself and does not cover items and services related to administration of the product.

Part B Covered Drugs in the Context of a Professional Service

Drugs furnished "Incident To" a Physician's Service. These are injectable or intravenous drugs that are administered predominantly by a physician or under a physician's direct supervision as "incident to" a physician's professional service. The statute limits coverage to drugs that are not usually self-administered.⁷ In order to meet all the general requirements for coverage under the "incident-to" provision, an FDA approved drug or biological *product* must:

- Be of a form that is not usually self-administered (as determined by the A/B *MAC* contractor);
- Must be furnished by a physician; and
- Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

The charge, if any, for the drug or biological *product* must be included in the physician's bill and the cost of the drug or biological *product* must represent an expense to the physician. Drug and biological *products* furnished by other health professionals may also meet these requirements.

⁷ If a drug is not self-administered by more than 50 percent of Medicare beneficiaries, it is considered "not usually self-administered".

Drugs furnished by a Medicare Advantage Organization “Incident To” a Physician’s Service. If a drug could be covered under Part B when furnished by a physician who incurred an expense in procuring the drug, it could also be covered under Part B in the case of a Medicare Advantage (MA) plan physician when the MA organization has incurred the expense of procuring the drug, and the drug is administered to an enrollee in the MA plan. Under Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 60.1, drugs can be covered as “incident to” physicians’ services if they “represent an expense to the physician or legal entity billing for the services or supplies.” Applying this principle to the case of a not-usually self administered drug administered by an MA plan physician to an MA plan enrollee, if the MA organization supplies the drug to the plan physician, it is the “legal entity billing” for the drug, since it is the entity that receives payment from Medicare that includes the cost of such a drug. Consequently, if the MA organization supplies the drug to the network provider, the MA organization should account for the drug under its A/B benefits. If a network pharmacy supplies the drug directly to the beneficiary, the drug must be accounted for under its Part D benefits.

Separately Billable ESRD Drugs. Most drugs furnished by dialysis facilities are separately billable. The largest Medicare expenditures for such drugs are for erythropoietin (EPO) which is covered for dialysis beneficiaries when it is furnished by independent and hospital-based ESRD facilities, as well as when it is furnished by physicians.

Separately billable drugs provided in Hospital Outpatient Departments. Medicare continues to pay separately for drug and biological *products*, and radiopharmaceuticals whose median cost per administration exceeds an amount (or threshold amount) determined by CMS, while packaging the cost of drugs, biological *products*, and radiopharmaceuticals whose median cost per administration is less than an amount (or threshold amount) determined by CMS into the procedures with which they are billed.

Drugs covered as Supplies or - “Integral to a Procedure.” Some drugs are covered as supplies that are an integral part of a procedure which is a diagnostic or therapeutic service, including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media. Other examples of drugs covered under the “integral to a procedure” provision include eye drops administered before cataract surgery.

Blood. Medicare does make separate payment for blood and *components*. *The Center for Biologics Evaluation and Research under the FDA regulates the collection of blood and blood components used for transfusion or for the manufacture of pharmaceuticals derived from blood and blood components.*

Drugs furnished as a part of a service in these provider settings. 1. Drugs packaged under the Hospital Outpatient Prospective Payment System (OPPS); 2. Drugs furnished by ESRD facilities and included in Medicare’s ESRD composite rate; 3. Osteoporosis drugs provided by home health agencies under certain conditions; 4. Drugs furnished by critical access hospitals’ (CAH) outpatient departments; 5. Drugs furnished by a rural health clinic (RHC); 6. Drugs furnished by federally qualified health centers (FQHC); 7. Drugs furnished by community mental health centers (CMHC); 8. Drugs furnished by ambulances; 9. Separately billable drugs provided in comprehensive outpatient rehabilitation facilities (CORF).

Part D Covered Drugs

Definition of a Part D Covered Drug

A Part D covered drug is available only by prescription, approved by the FDA (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Act), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug includes prescription drugs, biological products, insulin as described in specified paragraphs of section 1927(k) of the Act, vaccines licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration. The definition also includes medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes, can satisfy the definition of a Part D drug. CMS defines those medical supplies to include syringes, needles, alcohol swabs, gauze, and those supplies directly associated with delivering insulin into the body.

Part D Supplementary (Excluded) Drugs

The definition of a covered Part D drug excludes any drug for which as prescribed and dispensed or administered to an individual, payments would be available under Parts A or B of Medicare for that individual, even though a deductible may apply.

In addition, the definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents. The drugs or classes of drugs that may currently be otherwise restricted under Medicaid include:

- Agents when used for anorexia, weight loss, or weight gain (even if used for a non-cosmetic purpose (i.e., morbid obesity)).
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Agents when used for the treatment of sexual or erectile dysfunction (ED). ED drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction such as pulmonary hypertension. **However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug**

Information, and DRUGDEX® Information System. ED drugs meet the definition of a Part D drug only when used for FDA-approved indications.

While these drugs or uses are excluded from basic Part D coverage, Part D sponsors can generally include them as part of supplemental benefits, provided they otherwise meet the definition of a Part D drug. Because over-the-counter (OTC) drugs do not otherwise meet the definition of a Part D drug, they may not be included as part of supplemental benefits; however, under certain conditions as part of a plan utilization management program, OTC drugs can be provided at no cost to enrollees. The cost of these drugs to the Part D sponsor would be treated as administrative costs under such programs.

Other Resources

1. Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15. “Covered Medical and Other Health Services”. Section 110
2. Pub. 100-02, Medicare Benefit Policy Manual Chapter 15. “Covered Medical and Other Health Services” Section 50.2.
3. Reference Guide for Medicare Physician & Supplier Billers, Helping Front Office Personnel Navigate Medicare Rules for Part B Claims Processing. MedLearn Matters, Second Edition, October 2006.

Chapter 6 – Appendix C - Summary of Coverage Policy

ATTACHMENT I

Part B Drugs and Part D Coverage Chart

Drugs are covered under Part B in a variety of settings and under a variety of payment methodologies.

- Some drugs are paid on a cost basis or are part of a prospective payment, including: drugs packaged under the outpatient prospective payment system (OPPS); drugs furnished by End-Stage Renal Disease (ESRD) facilities and included in Medicare’s ESRD composite rate; osteoporosis drugs provided by home health agencies under certain conditions; and drugs furnished by: critical access hospitals’ outpatient departments (CAHs); rural health clinics (RHCs); federally qualified health centers (FQHCs); community mental health centers (CMHCs); and ambulances.
- In addition, there are 13 categories of drugs for which separate payment is made under Part B⁸, including: drugs furnished “incident to” a physician’s service; separately billable ESRD drugs; separately billable drugs provided in hospital outpatient departments; durable medical equipment (DME) supply drugs; drugs covered as supplies; drugs used in immunosuppressive therapy; blood clotting factors; certain vaccines; antigens; parenteral nutrition; certain oral drugs used in cancer treatment; separately billable drugs provided in comprehensive outpatient rehabilitation facilities (CORFs); and intravenous immune globulin provide in the home.⁹

The following chart groups the various categories of Part B coverage according to the extent to which they present some ambiguity for billing entities and/or Part D sponsors with regard to whether coverage should be under Part B or Part D. This ambiguity has different implications for stand alone Part D sponsors and for Medicare Advantage-Prescription Drug (MA-PD) Plans (including PACE plans and Section 1876 Cost plans which are treated similarly to MA-PDs). For stand alone Part D sponsors, the sponsor needs to determine whether it should make any payment. For MA-PDs, the MA organization needs to determine whether a payment should be assigned to its Part D spending or to its spending for Part B services.

⁸ If these drugs are provided as part of a Medicare Part A covered inpatient hospital or skilled nursing facility stay, they are generally bundled into the Medicare Part A payment to the facility. The exception with regard to inpatient hospital services is clotting factor which is paid separately. For covered SNF stays certain high cost chemotherapy drugs are billed separately along with preventive injections (e.g., flu shots). If a beneficiary does not have Part A coverage, if Part A coverage for the stay has run out or if a stay is non-covered, hospitals and SNFs can be paid for most categories of Part B covered drugs.

⁹ Medicare does make separate payment for blood and blood products under Part A and Part B. Although *the collection of blood and blood components used for transfusion or for the manufacture of pharmaceuticals derived from blood and blood components* are regulated by *the* FDA, they are not administered in a context that would not be covered under Part A or Part B. Therefore, generally these products are not Part D drugs. As a result, they are not included in this discussion.

A. Situations in which a billing entity would have to decide whether for a given drug to bill Part B or Part D based on characteristics of beneficiary or medical use of the drug.

Relationship between Part B and Part D Coverage	Categories of Separately Billable Part B Drugs	Comments
<p>1. The same drug dispensed by a pharmacy may be covered under Part B or Part D depending on the characteristics of the beneficiary.</p>	<p>Drugs used in immunosuppressive therapy for a transplant covered under Medicare.</p>	<p>Pharmacists would bill Part B or the individual’s Part D plan based on information received from the individual or the Part D plan. Part B would be billed if the individual had a Medicare-covered transplant; otherwise, the Part D plan would be billed. (Part D plan eligibility systems could contain a marker for members who had a Medicare covered transplant. This information could come from a question included on the Part D sponsor’s enrollment or coordination of benefit (COB) survey form.)</p> <p>In determining whether to pay for an immunosuppressive drug under Part D, it would not be appropriate for a Part D sponsor to institute a general policy of requiring a Part B claim rejection, as a substitute for maintaining information on transplant status and paying claims based on that information. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs. Instead a prior authorization requirement would be appropriate.</p>
<p>2. The same drug provided by an infusion/DME supplier may be covered under Part B or Part D depending on the characteristics of the beneficiary or method of administration.</p>	<p>a. Parenteral nutrition or intradialytic parenteral nutrition (IDPN) (for individuals with a non-functioning digestive tract).</p>	<p>The supplier would need to know whether the therapy was being provided because of a non-functioning digestive tract. If so, Part B would be billed. Otherwise this would be a Part D drug.</p> <p>It would not be appropriate for Part D sponsors to routinely require a rejection of a claim under Part B before processing a Part D claim. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs. However, if a Part D sponsor had evidence</p>

		<p>indicating that a particular claim for parenteral nutrition should be covered under Part B, it would be reasonable to require a rejection by Part B before processing in this case.</p>
	<p>b. Infusible DME supply drugs</p>	<p>In general, the supplier would bill Part B if the drug was administered using an infusion pump and bill the Part D plan for infusion using other methods (e.g., IV push). While professional services and supplies related to the administration of the infused drug are not payable under Part D, some coverage may be available under Part A or B home health benefits, under Medicaid, or from secondary commercial health benefits.</p> <p>As a rule, drugs infused using an implantable pump would be covered under Part B. Drugs infused in the home using an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare DME MAC. In the case of a beneficiary in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered -- infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. In this case, coverage for the drugs would be available under Part D. (see Attachment II, INFUSION DRUGS, Question 3 for other facilities which cannot be considered a beneficiary's "home" for DME purposes.)</p> <p>The fact that coverage is available for a particular drug under Part B with the use of an infusion pump does not mean that coverage under Part D using some other method of administration automatically can be denied. There is no Part B coverage in the home for infusion drugs administered without an</p>

		<p>infusion pump (e.g., IV push). There is also no Part B coverage in the home for infusion drugs administered with an infusion pump unless the drug is specifically covered under the local coverage policy of the applicable Medicare DME MAC. Therefore, determinations about Part D sponsor payment for these other methods of administration and for drugs administered with an infusion pump but not covered by the local DME MAC policy should be based on the question of whether the drug is on the sponsor's formulary.</p>
	<p>c. Intravenous immune globulin (IVIG) provided in the home for individual with diagnosis of primary immune deficiency disease</p>	<p>The supplier would bill Part B if the diagnosis is primary immune deficiency disease. IVIG provided in the home for other diagnoses would be a Part D benefit.</p> <p>As discussed above, it would not be appropriate, as a general rule, for Part D sponsors to require a rejection of a claim under Part B before processing a Part D claim. Prior authorization programs could be used to ensure medical necessity in accordance with the Part D sponsor's policy.</p>
<p>3. The same drug dispensed by a pharmacy may be covered under Part B or Part D depending on how the drug is used in treatment and the medical condition for which the drug is being prescribed.</p>	<p>a. Certain oral chemotherapy agents used in cancer treatment for which there is an infusible version of the drug.</p>	<p>Pharmacists would need to determine the reason for treatment. If related to cancer treatment, Part B would be billed; otherwise, the Part D plan should be billed.</p> <p>To the extent that a Part B-covered oral anti-cancer drug has no other medically accepted indication besides cancer treatment, Part D sponsors should not include these drugs on their formularies because of Part B coverage. For the drugs that have other medically accepted indications, prior authorization programs or other mechanisms to obtain diagnostic information could be used to ensure appropriate payment.</p>
	<p>b. Oral anti-emetics used in cancer treatment as a full replacement for intravenous treatment.</p>	<p>2. Pharmacists would need to determine the reason for treatment. If both related to cancer treatment and a full replacement for intravenous administration within 48 hours of cancer treatment, Part B would be billed; otherwise, the Part D plan should be</p>

		<p>billed. NOTE: In order to receive Part B payment, CMS currently requires that the prescribing physician indicate on the prescription that the oral anti-emetic is being used “as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen.”</p> <p>If based on a prior authorization program or other mechanism to obtain diagnostic information, a Part D sponsor determined that a) a Part B-covered oral anti-emetic was being billed, and b) the drug was being furnished in the context of cancer treatment for use within 48 hours of cancer treatment, the Part D sponsor should deny payment. Such drugs dispensed for use after the 48-hour period, or any oral anti-emetic prescribed for conditions other than the effects of cancer treatment, would be Part D drugs.</p>
4) The same vaccine may be covered under Part B or Part D depending on the characteristics of the beneficiary.	Hepatitis B vaccine for individuals at high or intermediate risk.	Physicians would need to determine the level of risk of the individual. If the individual is at high or intermediate risk, Part B would be billed. For all other individuals, prior authorization programs could be used to ensure appropriate level of risk.
B. Situation where the form of the drug determines where it is covered.		
Relationship between Part B and Part D Coverage	Categories of Separately Billable Part B Drugs	Comments
The same drug provided by a DME supplier or a pharmacy may be covered under Part B or Part D depending on its form (i.e., for use in nebulizer or in metered dose inhaler)	Inhalation DME supply drugs	<p>Certain inhalation drugs are generally covered under Part B when used with a nebulizer in the home. These drugs would not be covered under Part D for use with a nebulizer. However, if these drugs were delivered with a metered dose inhaler or other non-nebulized administration, they would be Part D drugs.</p> <p>In the case of a beneficiary in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered --</p>

		<p>inhalation DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. In this case, coverage for the drugs would be available under Part D. (See Attachment II, INFUSION DRUGS, Question 3 for other facilities which cannot be considered a beneficiary's "home" for DME purposes.)</p>
C. Situations where Part B coverage is in the context of another service.		
Relationship between Part B and Part D Coverage	Categories of Separately Billable Part B Drugs	Comments
<p>The same drug dispensed by a pharmacy is covered under Part B if provided as part of a service in a provider setting, physician's office or home.</p>	<ol style="list-style-type: none"> 1. Drugs furnished "incident to" a physician service 2. Separately billable ESRD drugs 3. Separately billable drugs in HOPDs 4. Separately billable drugs in CORFs 5. Drugs packaged under the OPSS 6. Drugs furnished by ESRD facilities and included in Medicare's ESRD composite rate 7. Osteoporosis drugs provided by home health agencies under certain conditions 	<p>Generally, if a beneficiary presents at a pharmacy with a script it would be a Part D drug. The availability of Part B coverage in a provider setting or physician's office should not result in a refusal of coverage under Part D for drugs dispensed by a pharmacy. This is the case because coverage is not available under Part B as the drug is being "prescribed and dispensed or administered" with respect to the individual. Thus, for example, while Part B covers certain injectables provided "incident to" a physician services, injectables dispensed by a pharmacy are not being "furnished" by a physician and would be Part D drugs.</p> <p>Part D sponsors should deny claims submitted by members for Part B-covered injectables if they are administered in a physician office from a physician's supply.</p> <p>Part D sponsors can subject injectables and infusables that would be covered under Part B as "incident to" a physician service, to a prior authorization program. To the extent that the sponsor determines based on medical literature that there exist serious</p>

	8. Drugs furnished by CAHs outpatient departments 9. Drugs furnished by RHCs 10. Drugs furnished by FQHCs 11. Drugs furnished by CMHCs 12. Drugs furnished by ambulances.	safety concerns such that it would go against accepted medical practice for a particular injectable or infusable to be dispensed directly to an enrollee, the claim can be denied as not "reasonable." Safety-based reasonableness determinations will need to be made on a case-by-case basis, since circumstances will vary. In general, however, there are very few instances when an injectable or infusable drug could not be reasonably dispensed directly to the patient.
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D. Completely unambiguous situations.

Relationship between Part B and Part D Coverage	Categories of Separately Billable Part B Drugs	Comments
1) Unique drugs never dispensed by a pharmacy.	Non-DME drugs covered as supplies (including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media.)	This category of drugs is those used for diagnostic or therapeutic purposes in a provider or physician office setting. CMS would assume that these drugs are not dispensed by pharmacies.
2) Drugs that would not be covered under Part D because of Part B coverage.	1. Blood clotting factors 2. Antigens Pneumococcal and influenza vaccines	These categories would not be a Part D benefit and should not be included on a Part D sponsor's formulary.

Chapter 6 – Appendix C - Summary of Coverage Policy

ATTACHMENT II

Part B v. Part D Drug Q's and A's

EXCLUSIONS RELATED TO MEDICARE COVERAGE UNDER PART A OR PART B

Question 1 – Should Part D sponsors deny claims for drugs covered under Part A or Part B of Medicare?

Answer 1 – Drugs, or uses of drugs, for which coverage is available under Part A or Part B are excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage. Unlike the list of supplementary drugs, these drugs, or uses of drugs, cannot be included in supplemental coverage.

There are two important considerations in determining whether a claim to Part D can be denied based on the availability of coverage under Part A or Part B of Medicare.

- First, the exclusion from the definition of a Part D drug for drugs covered under Parts A or B is based on whether coverage is available under Part A or Part B for the drug as it is being “prescribed and dispensed or administered” with respect to the individual. Thus, the same drug may be covered under different circumstances under both programs and coverage generally cannot be determined based solely on the drug itself. Since most Part B drug coverage is available in a provider setting or physician’s office rather than as drugs dispensed by pharmacists, there are very limited situations when a drug claim submitted by a pharmacy should be denied based on the availability of coverage under Part A or Part B.
- Second, to the extent a drug could be covered under part B as prescribed and dispensed or administered, Part D sponsors should view coverage as “available” under Part B regardless of whether or not an individual is actually enrolled in Part B.

Question 2 – Can a Part D sponsor require that coverage be denied under Part A or Part B before making payment under Part D?

Answer 2 – Generally, no. In limited instances, prior authorization programs may be necessary to determine whether the diagnosis of the individual or the particular use of a drug is consistent with Part D coverage, but it would not be appropriate to routinely require a denial from Part A or Part B before making payment in lieu of prior authorization. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs.

Question 3 - What happens if a Part D sponsor makes payment for a drug and later determines that the drug was covered under Part B as prescribed and dispensed or administered?

Answer 3 - If the drug as prescribed and dispensed or administered was covered under Part B on that day, the payment by the Part D sponsor would have been in error and it should seek recovery from the billing entity, which should bill Part B instead.

Question 4 - In the case of a newly approved drug that may be covered under one of the Part B benefit categories, can a Part D sponsor defer a coverage decision until Part B makes a decision?

Answer 4 - No. Once a drug is approved by the FDA it is a Part D drug. While it is not automatically a covered Part D drug, that is, it may not be included on a Part D sponsor's formulary, a member could request coverage on an exception basis.

For Medicare Part B coverage, a determination has to be made as to whether the approved drug fits in a benefit category (e.g., a drug covered as a supply of an external infusion pump used at home). In the vast majority of cases these determinations are delegated to the individual contractors. If a drug has a Medicare Part B benefit category and the drug is being "prescribed and dispensed or administered" as covered under Part B, the drug is no longer a Part D drug.

Question 5 - How will Part D sponsors determine whether a drug is covered under Part B?

Answer 5 - First, it is important to keep in mind that in most cases Part B drug coverage should not impact payment decisions by Part D sponsors since Part B coverage is generally in a provider setting or physician's office rather than for drugs dispensed at a pharmacy.

Payment for a particular drug can be denied only if there is Part B coverage as the drug is prescribed and dispensed or administered. The fact that a claim is received for a drug that is sometimes covered by Part B is not a basis for denial since the Part D sponsor would have to determine whether the drug is being prescribed and dispensed or administered on the basis under which Part B coverage is available. This will generally involve interaction between the Part D sponsor and the Medicare Part B contractor with jurisdiction in that geographic area for that drug.

With regard to new drugs, as decisions are made nationally or by individual A/B *MAC* contractors, this information will be available on the CMS and contractor Web sites.

INFUSION DRUGS

Question 1 - Since Part B covers infusion drugs in the home, can a Part D sponsor reject any claim for home infusion?

Answer 1 – No. Part B coverage is generally limited to a number of drugs that require the use of an infusion pump in the home. Any agents administered in the home via IV drip or push injection would be covered under Part D. This could include the same drugs that are covered under Part B when furnished through the use of an infusion pump.

Question 2 – Does Part B cover drugs that require an external infusion pump in the case of a beneficiary in a hospital or SNF bed who does not have Part A coverage, whose Part A coverage for the stay has run out or whose stay is non-covered?

Answer 2 – No, drugs that require an external infusion pump are not covered under Part B under those circumstances because the law limits coverage under Part B’s DME benefit to those items that are furnished for use in a patient’s home, and specifies that a hospital or SNF cannot be considered the beneficiary’s “home” for this purpose.

Question 3 - What other facilities cannot be considered the beneficiary’s “home” under the law for purposes of receiving the Medicare DME benefit?

Answer 3 – In addition to a hospital, a SNF or a distinct part SNF, the following facilities cannot be considered a home for purposes of receiving the Medicare DME benefit:

- a nursing home that is dually-certified as both a Medicare SNF and a Medicaid nursing facility (NF);
- a Medicaid-only NF that primarily furnishes skilled care;
- a non-participating nursing home (i.e., neither Medicare or Medicaid) that provides primarily skilled care; and
- an institution which has a distinct part SNF and which also primarily furnishes skilled care.

Question 4 - If the infusion services are furnished in an outpatient provider setting, can a Part D sponsor deny a claim?

Answer 4 – Yes. If a physician office or hospital outpatient department bill for infusion administered in those settings, the claim should always be denied because of coverage in those settings under Part B.

Question 5 – Since Part B covers intravenous immune globulin (IVIG) provided in the home, should a Part D sponsor deny claims for this drug?

Answer 5 – It depends. Part B coverage for IVIG in the home is for individuals whose diagnosis is primary immune deficiency disease. Part D would provide coverage for IVIG in the home for all other medically accepted indications. Prior authorization requirements could be used to ensure appropriate payment in accordance with the Part D sponsor’s medical necessity criteria. It would not be appropriate to routinely require a rejection of a claim under Part B before processing a Part D claim. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs.

Question 6 – Since Part B covers parenteral nutrition under certain circumstances, should Part D sponsors deny these claims?

Answer 6 – It depends. Part B coverage for parenteral nutrition is limited to individuals with a non-functioning digestive tract. So if parenteral nutrition is being provided based on this condition, the claim should be denied. For all other medically accepted indications, coverage

would be under Part D. Prior authorization programs could be used to ensure appropriate payment. As a general policy, it would not be appropriate to require a rejection of a claim under Part B before processing a Part D claim. However, if a Part D sponsor had a reasonable basis for assuming that a particular claim would be covered under Part B, it could require a rejection by Part B before processing.

ORAL ANTI-CANCER DRUGS

Question 1 - With regard to oral anti-neoplastics, we understand that if they have an IV form, they are covered under Part B. It is our thinking then, that we could exclude those that are used solely for cancer under this premise since they would be covered under Part B.

Answer 1 – Yes. Part D sponsors should not include on their formularies the oral anti-cancer agents covered by Part B whose only medically accepted indication is as an anti-cancer agent. They should always deny claims for these drugs. For the drugs that have other medically accepted indications, Part D sponsors should deny claims for these drugs when used for cancer treatment but when these drugs are used for other indications they would be Part D drugs. The use of the drug could be determined through a prior authorization program.

ORAL ANTI-EMETICS

Question 1 - Do pharmacies bill oral anti-emetics under Part B or Part D?

Answer 1 - It depends. Before billing either Part B or Part D, pharmacists would need to determine the reason for treatment. If it is related to cancer treatment and is a full replacement for intravenous administration within 48 hours of cancer treatment, Part B would be billed; otherwise, Part D should be billed.¹⁰ In order to receive Part B payment, CMS currently requires that the prescribing physician indicate on the prescription that the oral anti-emetic is being used “as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen.”

If (based on a prior authorization program) a Part D sponsor determines that a Part B-covered oral anti-emetic drug is being billed, and that the drug is being furnished in the context of cancer treatment for use within 48 hours of such treatment, the Part D sponsor should deny payment since coverage is available under Part B. Such drugs dispensed for use after the 48-hour period, or any oral anti-emetic prescribed for conditions other than treatment of the effects of cancer treatment, would be Part D drugs.

IMMUNOSUPPRESSANTS

Question 1 - Do pharmacies bill oral immunosuppressants under Part B or Part D?

¹⁰ There may be some local A/B **MAC** contractor variance regarding the 48 hour interval for the oral anti-emetics granisetron and dolasetron. Part D sponsors should contact their local A/B **MAC** contractor for more information regarding these drugs.

Answer 1 - It depends. Pharmacists would bill Part B or the individual's Part D plan based on information received from the individual or sources substantiating the patient's transplant. Part B would be billed if the individual had a Medicare covered transplant; otherwise, the Part D plan would be billed.

INJECTABLES

Question 1 - Can claims submitted by pharmacies for injectable drugs be denied based on Part B coverage in a physician office "incident to" a physician service?

Answer 1 – No. The exclusion from the definition of a Part D drug of drugs covered under Parts A or B is based on whether coverage is available under Part A or Part B for the drug as it is being "prescribed and dispensed or administered" with respect to the individual. Thus, the same drug may be covered under different circumstances under both programs. As a result, coverage cannot generally be determined based solely on the drug itself.

The fact that an injectable is covered under Part B in a physician's office or hospital outpatient department or other provider setting does not mean that these drugs should be excluded from the Part D sponsor's formularies, or that a Part D sponsor can deny a claim from a pharmacy based on availability of Part B coverage in a physician's office. If, however, a member submits an out-of-network claim for an injectable drug administered in-office from a physician's supply, and this drug is covered in that setting by the Part B contractor for that area, such a claim should be denied by the Part D sponsor based on Part B coverage. (Of course, an MA-PD plan would not deny such a claim, but rather pay it under the A/B benefit.)

Question 2 - An injectable drug that a Medicare contractor considers to be usually not self-administrable (e.g., injectable chemotherapy drugs) can only be covered under Part B as "incident to" a physician service if it is obtained by a physician and administered as part of a physician service. Can Part D sponsors require prior authorization for these medications when dispensed by a pharmacy? If the sponsor determines that the drug will be administered in a physician office, can the sponsor deny the claim because the practice of the patient taking the drug to the physician's office for administration is unsafe and because coverage is available under Part B if the physician obtained and administered the drug?

Answer 2 - Part D sponsors determine the scope of their own prior authorization programs subject to CMS review to ensure that such programs have a sound medical basis and do not discriminate against beneficiaries with certain medical conditions.

To the extent that a sponsor's prior authorization program applies to injectables and infusables that would be covered under Part B as "incident to" a physician's service, and the sponsor determines based on medical literature that there exist serious safety concerns such that it would go against accepted medical practice for a particular injectable or infusable to be dispensed directly to a member, the claim can be denied as not "reasonable." Thus, the dispensing of that particular drug to that member may be excluded by the Part D sponsor under Section 1862(a)(1)(A) of the Social Security Act as applied to Part D under 1860D-2(e)(3)(A) of the Act.

This same safety concern would not exist, however, if the claim for the drug was being submitted by an infusion supplier.

Safety-based reasonableness determinations will need to be made on a case-by-case basis, since circumstances will vary. In general, there are very few instances when an injectable or infusable drug could not be reasonably dispensed directly to the patient. All drugs are in some sense hazardous. This is not a unique characteristic of injectables and infusables.

Some situations that would present safety concerns in dispensing directly to a patient who is transporting the drug to a physician's office for administration include:

- The drug itself presents a bona fide public safety hazard (e.g., highly radioactive substance or an environmentally hazardous chemotherapeutic agent) that requires chain of custody handling to ensure use of appropriate equipment (i.e., safety hood) or persons of special qualifications.
- The drug requires special handling to preserve biologic activity and the patient is incapable or unwilling to do so. (For instance, a vaccine that must be kept frozen could be a problem if the patient had to transport it a long distance in summer heat.)
- The patient presents a high risk of diversion or inappropriate use. (For instance, giving a heroin addict a vial of morphine.)
- The patient has demonstrated unreliability, aversion, or unwillingness in transporting drugs to his doctor's office. (For instance, with respect to dispensing injectable psychiatric meds.)

In the absence of a serious safety concern based on the individual situation, however, there is no basis for denying a prescription presented at a pharmacy based on the availability of Part B coverage in another setting (e.g., physician office).

Finally, it is CMS' understanding that the practice of "brown-bagging" drugs is opposed by medical societies. CMS continues to urge them to reinforce this message with their members.

Question 3 – Most Medicare Advantage plans treat most non-self-injectables as a medical benefit. Do they have to treat them as a Part D benefit?

Answer 3 - If an injectable drug is covered under Part B in a provider or physician office setting, it will continue to be covered under Part B in those settings. If an injectable drug is not covered in a provider setting (e.g., determined by the contractor to be usually self-administered), then it will need to be covered under Part D. In addition, claims for non-Part-B-covered injectables whether usually self-administered or not, when dispensed and submitted by pharmacists could be covered under Part D. However, Part D plans could establish medical necessity criteria for limiting coverage of injectable drugs in physician offices.

Question 4 - What are Part D sponsors to do if their region includes multiple A/B *MAC* contractor areas and these contractors have differing policies with regard to injectable drugs?

Answer 4 – A Part D sponsor will have to modify its coverage based on the variation in Part B coverage across contractor areas within its region. That is, assume that there are two contractor areas within a Part D sponsor’s region, Contractor A and Contractor B. Further assume that Contractor A covers injectable X when furnished in a physician office but Contractor B does not. As a result of this difference in Part B coverage, injectable X is a Part D drug when furnished in a physician office for members residing in Contractor B’s area, but not in Contractor A’s area. In either area, injectable X would be covered under Part D if dispensed by a pharmacy.

For MA-PD plans, rules for selecting local coverage determinations apply. That is, if a local MA plan’s service area includes more than one contractor area, the plan may seek approval from CMS to apply uniformly to all of the plan’s enrollees local coverage policies that are the most beneficial to enrollees. Regional MA plans can select a set of local coverage policies to apply uniformly to their enrollees without CMS pre-approval. In either case, if the selected contractor covers injectable X, the MA-PD would treat injectable X as a basic A/B benefit. If the selected contractor does not cover injectable X, the MA-PD would treat it as a Part D drug.

Question 5 –What about new injectable drugs?

Answer 5 - As new injectables are approved by *the* FDA, Part B contractors or CMS would continue to make coverage decisions regarding drugs provided incident to a physician’s service based on whether the drug is “not usually self-administered.” Injectables not covered under Part B as incident to a physician’s service would become Part D drugs. However, there is no requirement for Part D sponsors to provide coverage of non-Part-B-covered drugs in the physician office setting if the drugs can be safely self-administered and there is no medical necessity for administration in that setting.

INHALATION DRUGS

Question 1 - Can claims submitted by a pharmacy for inhalation drugs delivered through metered-dose inhalers be denied based on Part B coverage of inhalation drugs used with a nebulizer?

Answer 1 – No. Since there currently is no coverage under Part B for inhalation drugs delivered through metered-dose inhalers and dispensed by a pharmacy, these drugs would be covered under Part D.

Question 2 – Does Part B cover inhalation drugs used with a nebulizer in the case of a beneficiary in a hospital or SNF bed who does not have Part A coverage, whose Part A coverage for the stay has run out or whose stay is non-covered?

Answer 2 – No, inhalation drugs used with a nebulizer are not covered under Part B under those circumstances because the law limits coverage under Part B’s DME benefit to those items that

are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. (See list above (**INFUSION DRUGS**, Question 3) for other facilities which cannot be considered a beneficiary's "home" for DME purposes.

VACCINES

Question 1 – Are all vaccines covered under Part D?

Answer 1 – No. There are a number of vaccines that remain covered under Part B. For instance, pneumococcal and influenza vaccines are not covered under Part D because of Part B coverage. Hepatitis B vaccine is covered under Part B for individuals at high or intermediate risk; for all other individuals, it would be covered under a Part D benefit. Part B also covers certain vaccines reasonable and necessary for the treatment of an illness or injury. All other currently available vaccines and all future preventative vaccines could be covered under Part D.

Question 2 - If a Part D sponsor determines through a prior authorization program that a hepatitis B vaccine is going to be administered by a physician can the Part D sponsor deny the claim based on Part B coverage in the setting?

Answer 2 – No. Since the Part B benefit for hepatitis B vaccine is separate from the "incident to" benefit, the determination about whether it is a Part D drug depends solely on characteristics of the beneficiary. However, if the Part D sponsor determines based on Medicare Part B guidelines that the individual is at high or medium risk for hepatitis B, the claim should be denied. For all other individuals, the vaccine would be a "Part D drug".

Question 3 - Medicare Part B covers hepatitis B vaccine for high and intermediate risk groups if ordered by a doctor of medicine or osteopathy, how are these groups defined?

Answer 3 – The high risk groups for whom vaccination is covered include:

- Individuals with End stage renal disease (ESRD);
- Individuals with hemophilia who received Factor VIII or IX concentrates;
- Clients of institutions for individuals for the mentally handicapped;
- Persons who live in the same household as a hepatitis B Virus (HBV) carrier;
- Homosexual men;
- Illicit injectable drug abusers

Intermediate risk groups include:

- Staff in institutions for the mentally handicapped; and
- Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

ANTIGENS

Question 1 – If a pharmacy submits a claim for antigens should a Part D sponsor make payment?

Answer 1 – No. Antigens are covered only under Part B.

BLOOD CLOTTING FACTORS

Question 1 – If a pharmacy submits a claim for blood clotting factors should a Part D sponsor make payment?

Answer 1 – No. Blood clotting factors are covered under Part A and Part B.

Chapter 6 – Appendix C - Summary of Coverage Policy

ATTACHMENT III

Web sites for Part B Coverage Information

Pub. 100-04, Medicare Claims Processing Manual	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html?DLPage=1&DLSort=0&DLSortDir=ascending
Pub. 100-02, Medicare Benefit Policy Manual	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html?DLPage=1&DLSort=0&DLSortDir=ascending
Medicare Coverage Database	http://www.cms.hhs.gov/mcd/search.asp
A/B MAC and DME MAC contact information	http://www.cms.hhs.gov/apps/contacts/

Chapter 6 - Appendix D

(Rev. 10, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

The Most Commonly Prescribed Drug Classes for the Medicare Population

3- HYDROXY- 3- METHYLGLUTARYL COENZYME A (HMG COA) REDUCTASE INHIBITORS	HORMONAL AGENTS, STIMULANT/ REPLACEMENT/ MODIFYING (THYROID)
5 ALPHA- REDUCTASE INHIBITORS	INSULIN, INTERMEDIATE- ACTING
ADENOSINE DIPHOSPHATE P2Y12 INHIBITORS	INSULIN, LONG- ACTING
ALPHA 1- ADRENERGIC BLOCKING AGENTS	INSULIN, SHORT- ACTING
ALPHA- ADRENERGIC AGONISTS	LAXATIVES
ALPHA- ADRENERGIC AGONISTS, OPHTHALMIC	LEUKOTRIENE RECEPTOR ANTAGONISTS
ANGIOTENSIN II RECEPTOR ANTAGONISTS	LINCOMYCIN ANTIBACTERIALS
ANGIOTENSIN- CONVERTING ENZYME (ACE) INHIBITORS	LOCAL ANESTHETICS
ANTI- INFLAMMATORIES, INHALED CORTICOSTEROIDS	LOOP DIURETICS
ANTIARRHYTHMICS - CLASS IA/ II/ III/ IV	LTC DRUGS- AMINO DERIVATIVE PENICILLINS (CHEWABLE)
ANTICHOLINERGICS	LTC DRUGS- AMINO DERIVATIVE PENICILLINS (ORAL LIQUID)
ANTICOAGULANTS	LTC DRUGS- ANTIEMETICS (SUPPOSITORY)
ANTIDEPRESSANTS, OTHER	LTC DRUGS- BRONCHODILATORS, SYMPATHOMIMETIC (SHORT- ACTING SOLUTION)
ANTIEMETICS	LTC DRUGS- HISTAMINE2 (H2) BLOCKING AGENTS (ORAL LIQUID)
ANTIHERPETIC AGENTS	LTC DRUGS- LOOP DIURETICS (ORAL LIQUID)
ANTISPASMODICS, GASTROINTESTINAL	LTC DRUGS- MACROLIDES (ORAL LIQUID)
ANTISPASMODICS, URINARY	LTC DRUGS- NONSTEROIDAL ANTI- INFLAMMATORY DRUGS (ORAL LIQUID)
ANTISPASTICITY AGENTS	MACROLIDES
ANXIOLYTICS	MISCELLANEOUS ANTIBACTERIALS
ATYPICALS	NICOTINIC ACID
AZOLE ANTIFUNGALS, ORAL	NITROFURAN ANTIBACTERIALS
BETA- ADRENERGIC BLOCKING AGENTS WITH VASODILATING PROPERTIES	NONSELECTIVE BETA- ADRENERGIC BLOCKING AGENTS
BETA- ADRENERGIC BLOCKING AGENTS, OPHTHALMIC	NONSTEROIDAL ANTI- INFLAMMATORY DRUGS
BETA- LACTAM, PENICILLINS	OPHTHALMIC AMINOGLYCOSIDES
BIGUANIDES	OPHTHALMIC ANTI- ALLERGY AGENTS

BIPOLAR AGENTS	OPHTHALMIC PROSTAGLANDIN AND PROSTAMIDE ANALOGS
BISPHOSPHONATES, ORAL	OPIOID ANALGESICS, LONG- ACTING
BOWEL PREPARATION PRODUCTS	OPIOID ANALGESICS, SHORT- ACTING
BRONCHODILATORS, ANTICHOLINERGIC	OPIOID ANALGESICS, SHORT- ACTING WITH APAP
BRONCHODILATORS, SYMPATHOMIMETIC (LONG- ACTING)	PHOSPHODIESTERASE III/ ADENOSINE UPTAKE INHIBITORS
BRONCHODILATORS, SYMPATHOMIMETIC (SHORT- ACTING)	POLYENE ANTIFUNGALS
CALCIUM CHANNEL BLOCKING AGENTS (NON-DIHYDROPYRIDINES)	POTASSIUM SUPPLEMENTS
CALCIUM CHANNEL MODIFYING AGENTS	POTASSIUM- SPARING DIURETICS
CARDIOSELECTIVE BETA- ADRENERGIC BLOCKING AGENTS	PROGESTINS
CARDIOVASCULAR AGENTS, OTHER	PROTECTANTS, GASTROINTESTINAL
CEPHALOSPORIN ANTIBACTERIALS, 1ST GENERATION	PROTON PUMP INHIBITORS
CEPHALOSPORIN ANTIBACTERIALS, 2ND GENERATION	QUINOLONES
CHOLESTEROL ABSORPTION INHIBITORS	SEDATIVES/ HYPNOTICS
CHOLINESTERASE INHIBITORS	SELECTIVE ESTROGEN RECEPTOR MODIFIERS
DIHYDROPYRIDINES	SEROTONIN/ NOREPINEPHRINE REUPTAKE INHIBITORS
DOPAMINE AGONISTS, NONERGOT	SKELETAL MUSCLE RELAXANTS
DOPAMINE PRECURSORS	SMOKING CESSATION AGENTS
ESTROGENS	SODIUM CHANNEL INHIBITORS
FIBRATES	SULFONAMIDES
GAMMA- AMINOBUTYRIC ACID (GABA) AUGMENTING AGENTS	SULFONYLUREAS
GLUCOCORTICOIDS, OPTHALMIC	TETRACYCLINES
GLUCOCORTICOIDS- SYSTEMIC	THIAZIDE DIURETICS
GLUCOCORTICOIDS- TOPICAL- MEDIUM POTENCY	THIAZOLIDINEDIONES
GLUCOCORTICOIDS-TOPICAL-HIGH POTENCY	TRICYCLICS
GLUTAMATE PATHWAY MODIFIERS	VASODILATORS, DIRECT- ACTING ARTERIAL
GLUTAMATE REDUCING AGENTS	VASODILATORS, DIRECT- ACTING ARTERIAL/ VENOUS
HISTAMINE1 (H1) BLOCKING AGENTS, MILDLY/ NON- SEDATING	XANTHINE OXIDASE INHIBITORS
HISTAMINE2 (H2) BLOCKING AGENTS	

Chapter 6 - Appendix E

Sample Transition Supply Scenarios and Eligibility

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

A Part D sponsor must provide for an appropriate transition process for certain enrollees who are prescribed Part D drugs that are non-formulary in order to promote continuity of care and avoid interruptions in drug therapy while a switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons can be effectuated. See Sections 30.4 – 30.4.11 for additional guidance.

Coverage Year 1	Coverage Year 2	Transition Eligible?
<i>Sponsor A Plan ABC (on formulary)</i>	<i>Sponsor A Plan ABC (on formulary)</i>	<i>No No change in formulary</i>
	<i>Sponsor A Plan ABC (non-formulary and/or new UM criteria)</i>	<i>Yes Negative change; potential interruption of coverage</i>
	<i>Sponsor A Plan EFG (on formulary)</i>	<i>No No change in formulary</i>
	<i>Sponsor A Plan EFG (non-formulary and/or UM criteria)</i>	<i>Yes Non-formulary change; potential interruption of coverage</i>
	<i>Sponsor B Plan JKL (on formulary)</i>	<i>No No interruption of coverage</i>
	<i>Sponsor B Plan JKL (non-formulary and/or UM criteria)</i>	<i>Yes Non-formulary change; potential interruption of coverage</i>
<i>Sponsor A Plan DEF (non- formulary) [filled under exception]</i>	<i>Any Sponsor Any Plan (on formulary)</i>	<i>No No interruption of coverage</i>
	<i>Sponsor A Plan DEF (non-formulary)</i>	<i>Yes Plans may approve an exception or transition to a formulary item prior to the new contract year</i>
	<i>Sponsor A Plan DEF (on formulary, with UM criteria)</i>	<i>Yes Plans may approve an exception or transition to a formulary item prior to the new contract year</i>
	<i>Sponsor B Plan MNO (non-formulary and/or UM criteria)</i>	<i>Yes Potential interruption of coverage</i>

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R18PDB	01/15/2016	Chapter 6 Part D Drugs and Formulary Requirements	01/15/2016	01/15/2016
R10PDB	02/12/2010	Chapter 6 Part D Drugs and Formulary Requirements	03/01/2010	N/A
<u>R2PDB</u>	07/18/2008	Initial release of chapter	07/18/2008	N/A