

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-02 Medicare Benefit Policy</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 157</b>	<b>Date: June 8, 2012</b>
	<b>Change Request 7847</b>

**SUBJECT: July 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**I. SUMMARY OF CHANGES:** CMS is providing several clarifications to the billing and payment rules in the Medicare Benefit Policy Manual for hospital outpatient physical therapy, occupational therapy, and speech language pathology services, and for drugs treated as hospital outpatient supplies.

**EFFECTIVE DATE: July 1, 2012**

**IMPLEMENTATION DATE: July 2, 2012**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	6/20/Outpatient Hospital Services
<b>R</b>	15/50.2/Determining Self-Administration of Drug or Biological

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding

continued performance requirements.

#### **IV. ATTACHMENTS:**

**Manual Instruction**

**Recurring Update Notification**

*\*Unless otherwise specified, the effective date is the date of service.*

# Attachment – Recurring Update Notification

Pub. 100-02	Transmittal: 157	Date: June 8, 2012	Change Request: 7847
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**SUBJECT: July 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**Effective Date: July 1, 2012**

**Implementation Date: July 2, 2012**

## **I. GENERAL INFORMATION**

**A. Background:** CMS is providing several clarifications to the billing and payment rules in the Medicare Benefit Policy Manual for hospital outpatient physical therapy, occupational therapy, and speech language pathology services, and for drugs treated as hospital outpatient supplies. CMS is also issuing changes to the supervision requirements for 28 Healthcare Common Procedure Coding System (HCPCS) codes, which are also available on the OPSS Website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/>.

## **B. Policy:**

### **1. Hospital Outpatient Therapy Services**

Medicare pays for physical therapy, occupational therapy, and speech language pathology services that are furnished to hospital outpatients at the applicable amount under the physician fee schedule. The manual language has been revised to clarify that the site of service and other requirements in chapter 6, section 20 do not apply to these services when they are furnished “as therapy,” meaning under a therapy plan of care. The paragraph on End Stage Renal Disease (ESRD) services has been edited to clarify that the requirements in section 20 do not apply to services that are covered and paid under the ESRD prospective payment system.

### **2. Drugs Treated as Hospital Outpatient Supplies**

In certain circumstances, Medicare pays for drugs that may be considered usually self-administered by the patient when such drugs function as hospital outpatient supplies. New information has been added to chapter 15, section 50.2 of the manual that clarifies when a hospital should consider and bill Medicare for a particular drug as a packaged supply and should not separately bill the beneficiary for the drug as a self-administered drug.

### **3. Supervision Levels for Hospital Outpatient Therapeutic Services**

In the Calendar Year (CY) 2012 OPSS /ASC Final Rule, CMS established a process to obtain independent advice from the Hospital Outpatient Payment Panel regarding the appropriate supervision levels for individual hospital outpatient therapeutic services. Based on the Panel’s recommendations to CMS at its meeting on February 27-28, 2012, CMS is issuing changes to the required supervision levels for 28 HCPCS codes effective July 1, 2012.

## II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement.

Use "Should" to denote an optional requirement.

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B  M A C	D M  M A C	F I  M A C	C A  R I E R	R H  I  S	Shared- System Maintainers	F I S S	M C S	V M S	C W F	OTHER	
7847.02.1	Medicare contractors shall refer to Pub.100-02, Medicare Benefit Policy Manual, Chapter 6, section 20, and Chapter 15, section 50.2 for the latest revisions.	X		X		X							

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B  M A C	D M  M A C	F I  M A C	C A  R I E R	R H  I  S	Shared- System Maintainers	F I S S	M C S	V M S	C W F	OTHER	
7847.02.2	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X		X							

#### IV. SUPPORTING INFORMATION

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A**

*Use "Should" to denote a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: For all other recommendations and supporting information, use this space: N/A**

#### V. CONTACTS

**Pre-Implementation Contact(s):** Marina Kushnirova at [marina.kushnirova@cms.hhs.gov](mailto:marina.kushnirova@cms.hhs.gov)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

#### VI. FUNDING

**Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*, use only one of the following statements:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**Attachment**

## **CMS' Final Decisions on the Recommendations of the Hospital Outpatient Payment Panel on Supervision Levels for Select Services**

In the Calendar Year (CY) 2012 Outpatient Prospective Payment System (OPPS) /Ambulatory Surgical Center (ASC) Final Rule, the Centers for Medicare & Medicaid Services (CMS) established a process to obtain independent advice from the Hospital Outpatient Payment Panel regarding the appropriate supervision levels for individual hospital outpatient therapeutic services (76 Fed. Reg.74360). CMS charged the Panel with recommending at the request of the Agency or the public the supervision level that will ensure the appropriate quality and safety for delivery of a given service as defined by its Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology code. In order to make its recommendations, the Panel uses clinical and other criteria that were established in the final rule.

On February 27-28, 2012, the Panel met and made recommendations to CMS regarding the supervision levels for 27 HCPCS codes. On April 18, 2012, in accordance with the final rule we posted our preliminary decisions based upon the Panel's recommendations on the OPSS website for public comment.

Most commenters supported our proposal to accept the Panel's recommendation that we change the requirement for the requested mental health services from direct supervision to general supervision. One medical specialty organization recommended that CMS include physicians who specialize in mental health services as Panel members so the Panel can make appropriate clinical judgments regarding the supervision of mental health services. While the commenter did not object to our proposal, the commenter recommended that CMS continue to evaluate the safety and quality of care to ensure that general supervision is appropriate and safe for the considered services. They requested that clinician stakeholders be able to share concerns with the Panel regarding proposed changes in supervision.

We encourage the nomination and participation of clinicians on the Panel who can best inform clinical issues regarding supervision levels. We are finalizing our proposed changes as follows effective July 1, 2012, and the following mental health services may be conducted under general supervision in accordance with applicable Medicare regulations and policies:

- HCPCS code 90804, *Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient*
- HCPCS code 90806, *Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient*
- HCPCS code 90808, *Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient*

- HCPCS code 90810, *Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient*
- HCPCS code 90812, *Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient*
- HCPCS code 90814, *Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient*
- HCPCS code 90816, *Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient*
- HCPCS code 90818, *Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient*
- HCPCS code 90821, *Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient*
- HCPCS code 90823, *Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient*
- HCPCS code 90826, *Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient*
- HCPCS code 90828, *Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient*
- HCPCS code 90846, *Family psychotherapy (without the patient present)*
- HCPCS code 90847, *Family psychotherapy (conjoint psychotherapy) (with patient present)*

- HCPCS code 90849, *Multiple-family group psychotherapy*
- HCPCS code 90853, *Group psychotherapy (other than of a multiple-family group)*
- HCPCS code 90857, *Interactive group psychotherapy*
- HCPCS code G0177, *Training and educational services related to the care and treatment of patient's disabling mental health problems per session (45 minutes or more)*
- HCPCS code G0410, *Group psychotherapy other than of a multiple-family group, in a partial hospitalization setting, approximately 45 to 50 minutes*
- HCPCS code G0411, *Interactive group psychotherapy, in a partial hospitalization setting, approximately 45 to 50 minutes*

In addition, commenters supported CMS' proposal to change the required supervision for the following services from direct supervision to general supervision. Effective July 1, 2012 these services may be conducted under general supervision in accordance with applicable Medicare regulations and policies:

- HCPCS code 51701, *Insertion of non-indwelling bladder catheter (e.g., straight catheterization for residual urine)*
- HCPCS code 90471, *Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)*
- HCPCS code 90472, *Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid) (list separately in addition to code for primary procedure)*
- HCPCS code 90473, *Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)*
- HCPCS code 90474, *Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid) (list separately in addition to code for primary procedure)*
- HCPCS code 99406, *Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes*
- HCPCS code 99407, *Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes*



Several commenters expressed concern about our proposal to reject the Panel's recommendation that we designate HCPCS code 94640, *Pressurized or nonpressurized inhalation treatment for acute airway obstruction or for sputum induction for diagnostic purposes (e.g., with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing [IPPB] device)*, as a non-surgical extended duration therapeutic service (extended duration service). Extended duration services require an initial period of direct supervision, but the patient may be transitioned to general supervision once he or she is stable at the discretion of the supervising practitioner. One commenter believed that the physician's presence should not be required for HCPCS code 94640 in the hospital, since this service can be performed by a patient at home. Others commented that since the Panel's charter does not prohibit the Panel from recommending extended duration services, it should be permitted to do so.

In the CY 2012 final rule, we indicated that the Panel may recommend only general, direct or personal supervision. HCPCS code 94640 is not performed over an extended period of time, and hospital patients receiving this service may require the supervising practitioner's presence depending on their condition. At a future Panel meeting the Panel may reevaluate the supervision level for this service. Therefore, we continue to require direct supervision for HCPCS code 94640.

# Medicare Benefit Policy Manual

## Chapter 6 - Hospital Services Covered Under Part B

### 20 - Outpatient Hospital Services

*(Rev. 157, Issued: 06-08-12, Effective: 07-01-12, Implementation: 07-02-12)*

Hospitals provide two distinct types of services to outpatients: services that are diagnostic in nature, and other services that aid the physician in the treatment of the patient. Part B covers both the diagnostic and the therapeutic services furnished by hospitals to outpatients. The rules *in this section* pertaining to the coverage of outpatient hospital services are not applicable to *the following services*.

- *Physical therapy, speech-language pathology or occupational therapy services when they are furnished “as therapy” meaning under a therapy plan of care. See chapter 15, sections 220 and 230 of this manual, for coverage and payment rules for these services, which are paid at the applicable amount under the physician fee schedule.*
- *Services that are covered and paid under the End Stage Renal Disease Prospective Payment System. See Chapter 11, “End Stage Renal Disease (ESRD)” of this manual, for rules on the coverage of these services.*

For policies *in addition to this section that apply* to partial hospitalization services, see chapter 6, section 70.3 *of this manual*, and *Pub. 100-04*, Medicare Claims Processing Manual, chapter 4, section 260.

For rules on the coverage of services and supplies furnished incident to a physician’s professional services in an office or physician-directed clinic setting, refer to Chapter 15, “Covered Medical and Other Health Services,” section 60 *of this manual*.

# Medicare Benefit Policy Manual

## Chapter 15 – Covered Medical and Other Health Services

### **50.2 - Determining Self-Administration of Drug or Biological**

*(Rev. 157, Issued: 06-08-12, Effective: 07-01-12, Implementation: 07-02-12)*

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) amended sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act to redefine this exclusion. The prior statutory language referred to those drugs “which cannot be self-administered.” Implementation of the BIPA provision requires interpretation of the phrase “not usually self-administered by the patient”.

#### **A. Policy**

Fiscal intermediaries, carriers and Medicare Administrative Contractors (MACs) are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor must make its own individual determination on each drug. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered. For example, an injectable drug used to treat migraine headaches is usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

#### **B. Administered**

The term “administered” refers only to the physical process by which the drug enters the patient’s body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Injectable drugs, including intravenously administered drugs, are typically eligible for inclusion under the “incident to” benefit. With limited exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are considered to be usually self-administered by the patient.

## C. Usually

For the purposes of applying this exclusion, the term “usually” means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it. In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered.

After determining whether a drug is usually self-administered for each indication, contractors should determine the relative contribution of each indication to total use of the drug (i.e., weighted average) in order to make an overall determination as to whether the drug is usually self-administered. For example, if a drug has three indications, is not self-administered for the first indication, but is self-administered for the second and third indications, and the first indication makes up 40 percent of total usage, the second indication makes up 30 percent of total usage, and the third indication makes up 30 percent of total usage, then the drug would be considered usually self-administered.

Reliable statistical information on the extent of self-administration by the patient may not always be available. Consequently, CMS offers the following guidance for each contractor’s consideration in making this determination in the absence of such data:

1. Absent evidence to the contrary, presume that drugs delivered intravenously are not usually self-administered by the patient.
2. Absent evidence to the contrary, presume that drugs delivered by intramuscular injection are not usually self-administered by the patient. (Avonex, for example, is delivered by intramuscular injection, not usually self-administered by the patient.) The contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:
  - A. **Acute Condition** - Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition were longer term, it would be more likely that the patient would self-administer the drug.
  - B. **Frequency of Administration** - How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.
3. Absent evidence to the contrary, presume that drugs delivered by subcutaneous injection are self-administered by the patient. However, contractors should examine the use of the particular drug and consider the following factors:

In some instances, carriers may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. Carriers may have exercised this discretion for limited coverage, for example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. Medicare will no longer pay for such doses. In addition, contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

#### **D. Definition of Acute Condition**

For the purposes of determining whether a drug is usually self-administered, an acute condition means a condition that begins over a short time period, is likely to be of short duration and/or the expected course of treatment is for a short, finite interval. A course of treatment consisting of scheduled injections lasting less than 2 weeks, regardless of frequency or route of administration, is considered acute. Evidence to support this may include Food and Drug Administration (FDA) approval language, package inserts, drug compendia, and other information.

#### **E. By the Patient**

The term “by the patient” means Medicare beneficiaries as a collective whole. The carrier includes only the patients themselves and not other individuals (that is, spouses, friends, or other care-givers are not considered the patient). The determination is based on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications. The carrier ignores all instances when the drug is administered on an inpatient basis.

The carrier makes this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis. In evaluating whether beneficiaries as a collective whole self-administer, individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question are not considered. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based. Note that some individuals afflicted with a less severe stage of an otherwise debilitating condition would be included in the population upon which the determination for “self-administered by the patient” was based; for example, an early onset of dementia.

#### **F. Evidentiary Criteria**

Contractors are only required to consider the following types of evidence: peer reviewed medical literature, standards of medical practice, evidence-based practice guidelines,

FDA approved label, and package inserts. Contractors may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Contractors should also use these evidentiary criteria when reviewing requests for making a determination as to whether a drug is usually self-administered, and requests for reconsideration of a pending or published determination.

Note that prior to August 1, 2002, one of the principal factors used to determine whether a drug was subject to the self-administered exclusion was whether the FDA label contained instructions for self-administration. However, CMS notes that under the new standard, the fact that the FDA label includes instructions for self-administration is not, by itself, a determining factor that a drug is subject to this exclusion.

### **G. Provider Notice of Noncovered Drugs**

Contractors must describe on their Web site the process they will use to determine whether a drug is usually self-administered and thus does not meet the “incident to” benefit category. Contractors must publish a list of the injectable drugs that are subject to the self-administered exclusion on their Web site, including the data and rationale that led to the determination. Contractors will report the workload associated with developing new coverage statements in CAFM 21208.

Contractors must provide notice 45 days prior to the date that these drugs will not be covered. During the 45-day time period, contractors will maintain existing medical review and payment procedures. After the 45-day notice, contractors may deny payment for the drugs subject to the notice.

Contractors must not develop local coverage determinations (LCDs) for this purpose because further elaboration to describe drugs that do not meet the ‘incident to’ and the ‘not usually self-administered’ provisions of the statute are unnecessary. Current LCDs based solely on these provisions must be withdrawn. LCDs that address the self-administered exclusion and other information may be reissued absent the self-administered drug exclusion material. Contractors will report this workload in CAFM 21206. However, contractors may continue to use and write LCDs to describe reasonable and necessary uses of drugs that are not usually self-administered.

### **H. Conferences Between Contractors**

Contractors’ Medical Directors may meet and discuss whether a drug is usually self-administered without reaching a formal consensus. Each contractor uses its discretion as to whether or not it will participate in such discussions. Each contractor must make its own individual determinations, except that fiscal intermediaries may, at their discretion, follow the determinations of the local carrier with respect to the self-administered exclusion.

## **I. Beneficiary Appeals**

If a beneficiary's claim for a particular drug is denied because the drug is subject to the "self-administered drug" exclusion, the beneficiary may appeal the denial. Because it is a "benefit category" denial and not a denial based on medical necessity, an Advance Beneficiary Notice (ABN) is not required. A "benefit category" denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug.

## **J. Provider and Physician Appeals**

A physician accepting assignment may appeal a denial under the provisions found in Pub. 100-04, Medicare Claims Processing Manual, chapter 29.

## **K. Reasonable and Necessary**

Contractors will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient's condition. Contractors will continue to make the determination of whether the intravenous or injection form of a drug is appropriate as opposed to the oral form. Contractors will also continue to make the determination as to whether a physician's office visit was reasonable and necessary. However, contractors should not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered in the physician's office or outpatient hospital setting. That is, while a physician's office visit may not be reasonable and necessary in a specific situation, in such a case an injection service would be payable.

## **L. Reporting Requirements**

Each carrier, intermediary and Medicare Administrative Contractor (MAC) must report to CMS its complete list of injectable drugs that the contractor has determined are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered. The CMS expects that contractors will review injectable drugs on a rolling basis and update their list of excluded drugs as it is developed and no less frequently than annually. For example, contractors should not wait to publish this list until every drug has been reviewed. Contractors must enter their self-administered drug exclusion list to the Medicare Coverage Database (MCD). This database can be accessed at [www.cms.hhs.gov/mcd](http://www.cms.hhs.gov/mcd). See Pub.100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.3, "*Policies and Guidelines Applied During Review*", for instructions on submitting these lists to the MCD.

## ***M. Drugs Treated as Hospital Outpatient Supplies***

*In certain circumstances, Medicare pays for drugs that may be considered usually self-administered by the patient when such drugs function as supplies. This is the case when*

*the drugs provided are an integral component of a procedure or are directly related to it, i.e., when they facilitate the performance of or recovery from a particular procedure. Except for the applicable copayment, hospitals may not bill beneficiaries for these types of drugs because their costs, as supplies, are packaged into the payment for the procedure with which they are used. Listed below are examples of when drugs are treated as supplies and hospitals should bill Medicare for the drug as a supply and should not separately bill the beneficiary.*

- *Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.*
- *Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre- and postoperatively.*
- *Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.*
- *Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.*
- *Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure.*

*The following are examples of when a drug is not directly related or integral to a procedure, and does not facilitate the performance of or recovery from a procedure. Therefore the drug is not considered a packaged supply. In many of these cases the drug itself is the treatment instead of being integral or directly related to the procedure, or facilitating the performance of or recovery from a particular procedure.*

- *Drugs given to a patient for his or her continued use at home after leaving the hospital.*
- *Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment.*
- *Daily routine insulin or hypertension medication given preoperatively to a patient.*
- *A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain.*
- *A laxative suppository for constipation while the patient waits to receive an unrelated X-ray.*



*These two lists of examples may serve to guide hospitals in deciding which drugs are supplies packaged as a part of a procedure, and thus may be billed under Part B. Hospitals should follow CMS' guidance for billing drugs that are packaged and paid as supplies, reporting coded and uncoded drugs with their charges under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs.*