**Instructions to Health Plans**

* [*Plans are subject to the notice requirements under Section 1557 of the Affordable Care Act. For more information, refer to* [*https://www.hhs.gov/civil-rights/for-individuals/section-1557*](https://www.hhs.gov/civil-rights/for-individuals/section-1557)*.*]
* [Plans should replace “Medicaid” with “Medi-Cal”.]
* [If plans do not use the term “Member Services,” plans should replace it with the term the plan uses.]
* [Where the template instructs inclusion of a phone number, plans must ensure it is a toll-free number and include a toll-free TTY/TDD number and days and hours of operation.]
* [Plans should note that the EOC is referred to as the “Member Handbook.” If plans do not use the term “Member Handbook,” plans should replace it with the term the plan uses.]
* [Plans should include all drugs/items covered under the Part D and Medi-Cal pharmacy benefits. *This includes only those drugs on plans’ approved Part D formulary and approved Additional Demonstration Drug (ADD) file. Plans may not include OTC drugs and/or items offered as a plan supplemental benefit that are in excess of Medi-Cal-required OTC drugs and/or items.*]
* [Plans may place a QR code on materials to provide an option for members to go online.]
* [The footer should appear on every other page. Plans have the option of deleting the footer following the introduction (e.g., the footer is not necessary in the actual list of drugs)]
* [*Wherever possible, plans are encouraged to adopt good formatting practices that make information easier for English-speaking and non-English speaking enrollees to read and understand. The following are based on input from beneficiary interviews:*
* *Format a section, chart, table, or block of text to fit onto a single page. In instances where an item or text continues on to the following page, enter a blank return before right aligning with clear indication that the item continues (for example, as in the Benefits Chart in Chapter 4 of the Member Handbook, insert:* **This section is continued on the next page***).*
* *Ensure plan-customized text is in plain language and complies with reading level requirements established in the three-way contract.*
* *Break up large blocks of plan-customized text into short paragraphs or bulleted lists and give a couple of plan-specific examples as applicable.*
* *Spell out an acronym or abbreviations before its first use in a document or on a page (for example, Long-term services and supports (LTSS) or low-income subsidy (LIS)).*
* *Include the meaning of any plan-specific acronym, abbreviation, or key term with its first use.*
* *Avoid separating a heading or subheading from the text that follows when paginating the model.*
* *Use universal symbols or commonly understood pictorials.*
* *Draft and format plan-customized text and terminology in translated models to be culturally and linguistically appropriate for non-English speakers.*
* *Consider using regionally appropriate terms or common dialect in translated models.*
* *Include instructions and navigational aids in translated models in the translated language rather than in English.*
* *Consider producing translated models in large print.*]

**<Plan Name> | <year> *List of Covered Drugs* (Formulary)**

**Introduction**

This document is called the *List of Covered Drugs* (also known as the Drug List).It tells you which prescription drugs [*insert if applicable:* and over-the-counter] drugs [*insert if applicable:* and items] are covered by <plan name>. The Drug Listalso tells you if there are any special rules or restrictions on any drugs covered by <plan name>. Key terms and their definitions appear in the last chapter of the *Member Handbook*.

[In accordance with Section 60.4 of the Medicare Marketing Guidelines (MMG), plans must indicate when the document was last updated by including either “Updated MM/YYYY” or “No changes made since MM/YYYY.” Plans must include their contact information on both the front and back cover in accordance with Section 60.4.1 of the MMG.]

[*Plans must update the Table of Contents to this document to accurately reflect where the information is found on each page after plan adds plan-customized information to this template.*]

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1. Disclaimers

This is a list of drugs that members can get in <plan name>.

* [*Plans must include all applicable disclaimers as required in the Medicare Communications and Marketing Guidelines and State-specific Marketing Guidance.*]
* ATTENTION: If you speak [*insert language of the disclaimer*], language assistance services, free of charge, are available to you. Call [insert Member Services toll-free phone and TTY/TDD numbers, and days and hours of operation]. The call is free. [*This disclaimer must be included in* all non-English languages that meet the Medicare and/or state thresholds for translation.]
* You can get this document for free in other formats, such as large print, braille, or audio. Call [insert Member Services toll-free phone and TTY/TDD numbers, and days and hours of operation]. The call is free.
* [*Plans must also describe how members can make a standing request to get this document, now and in the future, in a language other than English or in an alternate format.*]

1. Frequently Asked Questions (FAQ)

Find answers here to questions you have about this *List of Covered Drugs*. You can read all of the FAQ to learn more, or look for a question and answer.

B1. What prescription drugs are on the *List of Covered Drugs*? (We call the *List of Covered Drugs* the “Drug List” for short.)

The drugs on the Drug List are the drugs covered by <plan name>. The drugs are available at pharmacies within our network. A pharmacy is in our network if we have an agreement with them to work with us and provide you services. We refer to these pharmacies as “network pharmacies.”

* <Plan name> will cover all medically necessary drugs on the Drug List if:
* your doctor or other prescriber says you need them to get better or stay healthy, **and**
* you fill the prescription at a <plan name> network pharmacy.
* In some cases, you have to do something before you can get a drug (see question B4 below).

You can also see an up-to-date list of drugs that we cover on our website at <web address> or call Member Services at <toll-free number>.

B2. Does the Drug List ever change?

Yes. <Plan name> may add or remove drugs on the Drug List during the year.

We may also change our rules about drugs. For example, we could:

* Decide to require or not require prior approval for a drug. (Prior approvalis permission from <plan name> before you can get a drug.)
* Add or change the amount of a drug you can get (called quantity limits).
* Add or change step therapy restrictions on a drug*.* (Step therapy means you must try one drug before we will cover another drug.)

For more information on these drug rules, see question B4.

If you are taking a drug that was covered at the **beginning** of the year, we will generally not remove or change coverage of that drug **during the rest of the year** unless:

* a new, cheaper drug comes along that works as well as a drug on the Drug List now, **or**
* we learn that a drug is not safe, **or**
* a drug is removed from the market.

Questions B3 and B6 below have more information on what happens when the Drug List changes.

* You can always check <plan name>’s up to date Drug List online at <web address>.
* You can also call <Member Services> to check the current Drug List at <toll-free number>.

B3. What happens when there is a change to the Drug List?

Some changes to the Drug List will happen **immediately**. For example:

* [*Plans that otherwise meet all requirements and want the option to immediately replace brand name drugs with their generic equivalents must provide the following advance general notice of changes:* **A new generic drug becomes available**. Sometimes, a new and cheaper drug comes along that works as well as a drug on the Drug List now. When that happens, we may remove the current drug, but your cost for the new drug will stay the same [*insert if applicable, for example, if the plan’s Drug List has differential cost-sharing for some generics:* or will be lower]. When we add the new generic drug, we may also decide to keep the current drug on the list but change its coverage rules or limits.
  + We may not tell you before we make this change, but we will send you information about the specific change or changes we made.
  + You or your provider can ask for an exception from these changes. We will send you a notice with the steps you can take to ask for an exception. Please see question B10 for more information on exceptions.]
* **A drug is taken off the market**. If the Food and Drug Administration (FDA) says a drug you are taking is not safe or the drug’s manufacturer takes a drug off the market, we will take it off the Drug List. If you are taking the drug, we will let you know. [*Plans should include information advising beneficiaries what to do after they are notified (e.g., contact the prescribing doctor, etc.).*]

**We may make other changes that affect the drugs you take.** We will tell you in advance about these other changes to the Drug List. These changes might happen if:

* The FDA provides new guidance or there are new clinical guidelines about a drug.
* [*Plans that want the option to immediately substitute a new generic drug, insert:* We add a generic drug that is not new to the market **and**
  + Replace a brand name drug currently on the Drug List **or**
  + Change the coverage rules or limits for the brand name drug.]
* [*Plans that are not making immediate generic substitutions insert:* We add a generic drug **and** 
  + Replace a brand name drug currently on the Drug List **or**
  + Change the coverage rules or limits for the brand name drug.]

When these changes happen, we will tell you at least 30 days before we make the change to the Drug List **or** when you ask for a refill. This will give you time to talk to your doctor or other prescriber. He or she can help you decide if there is a similar drug on the Drug List you can take instead or whether to ask for an exception. Then you can:

* Get a [*insert supply limit (must be at least the number of days in the plan’s one-month supply)*]-day supply of the drug before the change to the Drug List is made, or
* Ask for an exception from these changes. Please see question B10 for more information about exceptions.

B4. Are there any restrictions or limits on drug coverage or any required actions to take to get certain drugs?

Yes, some drugs have coverage rules or have limits on the amount you can get. In some cases you or your doctor or other prescriber must do something before you can get the drug. For example [*Plans should omit bullets as needed and reflect only those utilization management procedures actually used by the plan*]:

* **Prior approval (or prior authorization):** For some drugs, you or your doctor or other prescriber must get approval from <plan name> before you fill your prescription. <Plan name> may not cover the drug if you do not get approval.
* **Quantity limits:** Sometimes <plan name> limits the amount of a drug you can get.
* **Step therapy:** Sometimes <plan name> requires you to do step therapy. This means you will have to try drugs in a certain order for your medical condition. You might have to try one drug before we will cover another drug. If your doctor thinks the first drug doesn’t work for you, then we will cover the second.

You can find out if your drug has any additional requirements or limits by looking in the tables on pages <page numbers>. You can also get more information by visiting our web site at <web address>. [Plans that apply prior authorization and/or step therapy insert the following with applicable information: We have posted online [insert: a document or documents] that [insert: explains or explain] our [insert as applicable: prior authorization restriction **or** step therapy restriction **or** prior authorization and step therapy restrictions.]You may also ask us to send you a copy.

You can ask for an exception from these limits. This will give you time to talk to your doctor or other prescriber. He or she can help you decide if there is a similar drug on the Drug List you can take instead or whether to ask for an exception. Please see questions B10-B12 for more information about exceptions.

B5. How will you know if the drug you want has limitations or if there are required actions to take to get the drug?

The *List of Covered Drugs* on page <page number> has a column labeled “Necessary actions, restrictions, or limits on use.”

B6. What happens if we change our rules about some drugs (for example, prior authorization (approval), quantity limits, and/or step therapy restrictions)?

[*Plans should omit information as needed and reflect only those utilization management procedures actually used by the plan*]: In some cases, we will tell you in advance if we add or change prior approval, quantity limits, and/or step therapy restrictions on a drug. See question B3 for more information about this advance notice and situations where we may not be able to tell you in advance when our rules about drugs on the Drug List change.

##### B7. How can you find a drug on the Drug List?

There are two ways to find a drug:

* You can search alphabetically (if you know how to spell the drug), **or**
* You can search by medical condition.

To search **alphabetically**, go to the Index of Covered Drugs section. You can find it [give instructions].

To search **by medical condition**, find the section labeled “List of drugs by medical condition” on page <page number>. The drugs in this section are grouped into categories depending on the type of medical conditions they are used to treat. For example, if you have a heart condition, you should look in the category, <therapeutic category name example>. That is where you will find drugs that treat heart conditions.

B8. What if the drug you want to take is not on the Drug List?

If you don’t see your drug on the Drug List, call Member Services at <toll-free number> and ask about it. If you learn that <plan name> will not cover the drug, you can do one of these things:

* Ask Member Services for a list of drugs like the one you want to take. Then show the list to your doctor or other prescriber. He or she can prescribe a drug on the Drug List that is like the one you want to take. **Or**
* You can ask the health plan to make an exception to cover your drug. Please see questions B10-B12 for more information about exceptions.

B9. What if you are a new <plan name> member and can’t find your drug on the Drug List or have a problem getting your drug?

We can help. We may cover a temporary [insert supply limit (must be the number of days in plan’s one-month supply)]-day supply of your drug during the first [must be at least 90]days you are a member of <plan name>. This will give you time to talk to your doctor or other prescriber. He or she can help you decide if there is a similar drug on the Drug List you can take instead or whether to ask for an exception.

If your prescription is written for fewer days, we will allow multiple fills to provide up to a maximum of [*insert supply limit (must be the number of days in plan’s one-month supply)*] days of medication.

We will cover a [*insert supply limit (must be the number of days in plan’s one-month supply)*]-day supply of your drug if:

* you are taking a drug that is not on our Drug List, **or**
* health plan rules do not let you get the amount ordered by your prescriber, **or**
* the drug requires prior approval by <plan name>, **or**
* you are taking a drug that is part of a step therapy restriction.

If you are in a nursing home or other long-term care facility and need a drug that is not on the Drug List or if you cannot easily get the drug you need, we can help. If you have been in the plan for more than[*insert time period (must be at least 90 days)*] days, live in a long-term care facility, and need a supply right away:

* We will cover one [*insert supply limit (must be at least a 31-day supply)*]supply of the drug you need (unless you have a prescription for fewer days), whether or not you are a new <plan name> member.
* This is in addition to the temporary supply during the first [*must be at least 90*] days you are a member of <plan name>.

[*If applicable, plans must insert a description of their transition policy for current members with changes to their level of care, as specified in section 30.4.7 of Chapter 6 of the Prescription Drug Benefit Manual.*]

B10. Can you ask for an exception to cover your drug?

Yes. You can ask <plan name> to make an exception to cover a drug that is not on the Drug List.

You can also ask us to change the rules on your drug.

* For example, <plan name> may limit the amount of a drug we will cover. If your drug has a limit, you can ask us to change the limit and cover more.
* Other examples: You can ask us to drop step therapy restrictions or prior approval requirements.

B11. How can you ask for an exception?

To ask for an exception, call [plans should include information on the best person to call – e.g., your care coordinator **or** your care team **or** Member Services]. [Insert: Your care coordinator **or** Your care team **or** Member Services] will work with you and your provider to help you ask for an exception. You can also read Chapter 9, [*plans may insert a reference, as applicable*], of the *Member Handbook* to learn more about exceptions.

B12. How long does it take to get an exception?

First, we must get a statement from your prescriber supporting your request for an exception. After we get the statement, we will give you a decision on your exception request within 72 hours.

If you or your prescriber think your health may be harmed if you have to wait 72 hours for a decision, you can ask for an expedited exception. This is a faster decision. If your prescriber supports your request, we will give you a decision within 24 hours of getting your prescriber’s supporting statement.

B13. What are generic drugs?

Generic drugs are made up of the same ingredients as brand name drugs. They usually cost less than the brand name drug and their names are less commonly known. Generic drugs are approved by the Food and Drug Administration (FDA).

<Plan name> covers both brand name drugs and generic drugs.

B14. What are OTC drugs?

OTC stands for “over-the-counter”. <Plan name> covers some OTC drugs when they are written as prescriptions by your provider.

You can read the <plan name> Drug List to see what OTC drugs are covered.

[*Plans should include OTC drugs they pay for and that were included on the integrated formulary approved by CMS and the state in the Drug List. They should provide cost-sharing information there as well*.]

B15. Does <plan name> cover OTC non-drug products?

<Plan name> covers some OTC non-drug products when they are written as prescriptions by your provider.

[*Plans should include the following language*: Examples of OTC non-drug products include <examples of plan’s covered OTC non-drug products>.]

You can read the <plan name> Drug List to see what OTC non-drug products are covered.

[Plans should include OTC non-drug products they pay for in the Drug List. They should provide cost-sharing information there as well.]

B16. What is your copay?

[*Plans with no copays in any tier insert:* As a <plan name> member, you have no copays for prescription and OTC drugs as long as you follow <plan name>’s rules.]

[*Plans with copays in any tier insert:* You can read the <plan name> Drug List to learn about the copay for each drug.] <Plan name> members living in nursing homes or other long-term care facilities will have no copays. Some members getting long-term care in the community will also have no copays.

[Plans with copays in any tier must also provide an explanation; see the example of tiered copays below. Plans should modify the explanation below consistent with their tier model, to include the range of applicable cost sharing amounts for each tier (and a statement that the copay varies depending on the person’s level of Medi-Cal eligibility), and a description of the types of drugs (e.g., generics, brands, and/or OTCs) on each tier. *Plans must ensure the tier label or description of the types of drugs on each tier is consistent with the guidance regarding generic tier labels in the CY 2016 Final Call Letter.* If a plan has no copays for one or more tiers of drugs, the plan should modify the copay information accordingly.

Copays are listed by tiers. Tiers are groups of drugs with the same copay.

* Tier 1 drugs have the lowest copay. They may be generic drugs or non-Medicare drugs that are covered by Medi-Cal. The copay is from <amount> to <amount>, depending on your income.
* Tier 2 drugs have a medium copay. They are brand name drugs. The copay is from <amount> to <amount>, depending on your income.
* Tier 3 drugs have the highest copay. They have a copay of <amount>.]

B17. What are drug tiers?

[*Only plans with no copays in any tier should include question B17*.]

Tiers are groups of drugs on our Drug List.

[*Plans must provide a description of each of their drug tiers and the types of drugs (e.g., generic, brand, and/or OTC) in each tier.*

*Plans with no copays in any tier include tier examples such as the following:*

* Tier 1 drugs are generic drugs.
* Tier 2 drugs are brand name drugs.

*Plans must ensure the tier label or description of the types of drugs on each tier is consistent with the guidance regarding generic tier labels in the CY 2016 Final Call Letter and consistent with their approved plan benefit package. Plans must also include a statement that all tiers have no copay*.]

1. List of Covered Drugs

The following list of covered drugs gives you information about the drugs covered by <plan name>. If you have trouble finding your drug in the list, turn to the Index of Covered Drugs that begins on page <index page number>. The Index alphabetically lists all drugs covered by <plan name>.

The first column of the chart lists the name of the drug. Brand name drugs are capitalized (e.g., <BRAND NAME EXAMPLE>) and generic drugs are listed in lower-case italics (e.g., *<generic example>*).

The information in the “Necessary actions, restrictions, or limits on use” column tells you if <plan name> has any rules for covering your drug.

[**Note:** Plans must *provide information on the following items when applicable to specific drugs and* explain any symbols or abbreviations used to indicate *their application:* utilization management restrictions, drugs that are available via mail-order, free first fill drugs, limited access drugs, and drugs covered under the medical benefit (for home infusion drugs only). *While the symbols and abbreviations must appear whenever applicable, plans are not required to provide associated explanations on every page. They must, however, provide a general footnote on every page stating:* You can find information on what the symbols and abbreviations in this table mean by going to[*insert description of where information is available, such as page number*].]

[***Note:***Any OTC drugs or products on the plan’s approved integrated formulary must be included on the Drug List. For non–Part D drugs or OTC items that are covered by Medi-Cal, please place an asterisk (\*) or another symbol by the drug to indicate that the beneficiary may need to follow a different process for appeals.]

**Note:** The [insert symbol used by the plan] next to a drug means the drug is not a “Part D drug.” You will not be required to pay a copay for these drugs. These drugs also have different rules for appeals.

* An appeal is a formal way of asking us to review a decision we made about your coverage and to change it if you think we made a mistake. For example, we might decide that a drug that you want is not covered or is no longer covered by Medicare or Medi-Cal.
* If you or your doctor disagrees with our decision, you can appeal. If you ever have a question, call Member Services at <toll-free number>. You can also read Chapter 9, [*plans may insert a reference, as applicable*] of the *Member Handbook* to learn how to appeal a decision.

1. List of Drugs by Medical Condition

The drugs in this section are grouped into categories depending on the type of medical conditions they are used to treat. For example, if you have a heart condition, you should look in the category, <therapeutic category name example>. That is where you will find drugs that treat heart conditions.

[*If plans use codes in the “Necessary actions, restrictions, or limits on use” column, they should include a key. Plans are not required to include a key on every page, but plans must provide a general footnote on every page stating:* You can find information on what the symbols and abbreviations in this table mean by going to[*insert description of where information is available, such as page number*]. *The key below is only an example. Plans do not have to use the same abbreviations/codes.*]

Here are the meanings of the codes used in the “Necessary actions, restrictions, or limits on use” column:

(g) = Only the generic version of this drug is covered. The brand name version is not covered.

M = The brand name version of this drug is in Tier 3. The generic version is in Tier 1.

PA = Prior authorization (approval): you must have approval from the plan before you can get this drug.

ST = Step therapy: you must try another drug before you can get this one.

[*Plans have the option to insert a table to illustrate drugs either by therapeutic category or by therapeutic category further divided into classes. An example of each type of table is presented below.*]

**<Therapeutic Category> –** [*Optional: Plans are encouraged to insert a plain language description of the category. Plans include additional therapeutic categories as needed.*]

| Name of drug | What the drug will cost you (tier level) | Necessary actions, restrictions, or limits on use |
| --- | --- | --- |
| <AZASAN> | <$0–$3 (Tier 3)> | <PA> |
|  |  |  |
|  |  |  |

**or**

**<Therapeutic Category> –** [*Optional: Plans are encouraged to insert a plain language description of the category. Plans include additional therapeutic categories further divided into classes as needed.*]

| Name of drug | What the drug will cost you (tier level) | Necessary actions, restrictions, or limits on use | |
| --- | --- | --- | --- |
| *<Therapeutic Class Name 1> -* [*Optional: <Plain Language Description>*] | | |
| <Drug Name 1> | <Tier Level> | <Util. Mgmt.> | |
| <Drug Name 2> | <Tier Level> | <Util. Mgmt.> | |
| *<Therapeutic Class Name 2> -* [*Optional: <Plain Language Description>*] | | |
| <Drug Name 1> | <Tier Level> | <Util. Mgmt.> | |
| <Drug Name 2> | <Tier Level> | <Util. Mgmt.> | |

###### **[General Drug Table instructions:**

Column headings should be repeated on each page of the table.

Plans should include OTC drugs they pay for and that were included on the integrated formulary approved by CMS and the state in the Drug List. They should provide cost-sharing information there as well.

Plans should include OTC non-drug products they pay for in the Drug List. They should provide cost-sharing information there as well.

Plans may include a “plain-language” description of the *therapeutic* category next to the name of each category. For example, instead of only including the category “Dermatological Agents,” plans may include “Dermatological Agents – Drugs to treat skin conditions.”

List *therapeutic* categories alphabetically within the table, and list drugs alphabetically under the appropriate *therapeutic* category. If plans use the second option and further divide the categories into classes, the therapeutic categories should be listed alphabetically and the therapeutic classes listed alphabetically under the appropriate category. The drugs should then be listed alphabetically under the appropriate therapeutic class.

The chart must include at least two covered drugs for each therapeutic category or class except when only one drug exists in the category or class or when two drugs exist in the category or class but one is clinically superior to the other as per your CMS-approved formulary.]

###### [**“Name of Drug” column instructions:**

Brand name drugs should be capitalized (e.g., DRUG A). Generic drugs should be lowercase and italicized (e.g., penicillin). Plans may include the generic name of a drug next to the brand name.

*If there are differences in formulary status, tier placement, quantity limit, prior authorization, step therapy, or other restrictions or benefit offerings (e.g., available via mail order, etc.) for a drug based on its differing dosage forms or strengths, the formulary must clearly identify how it will treat the different formulations of that same drug. For instance, if a drug has a different tier placement depending on the dosage (e.g., 20 mg is in Tier 1 and 40 mg is in Tier 4), plans must include the drug twice within the table with the varying dosage listed next to the drug name (e.g., DRUG A, 20 mg and DRUG A, 40 mg). The drug will be counted as a single drug when determining whether the plan has included two drugs within each therapeutic category/class.*]

###### [**“What the drug will cost you (tier level)” column instructions:**

Plans should put the appropriate tier level in parentheses next to the copay or range of copays as shown in the example above.]

###### [**Necessary actions, restrictions, or limits on use column instructions**

Plans may include abbreviations within this column (e.g., QL for quantity limits) but must include an explanation at the beginning of the table explaining each abbreviation.

Plans must explain any symbols or abbreviations used to show use restrictions, drugs that are available via mail order, non-Part D drugs or OTC items that are covered by Medi-Cal, free-first-fill drugs, limited-access drugs, and drugs covered under the medical benefit (for home infusion drugs only and for plans that specifically request and are approved in the plan benefit package to bundle home infusion drugs and services under the medical benefit). Plans may also use abbreviations to show drugs that are not available via mail-order.

**Note:** Health plans may want to add this bullet if the plan offers generic use incentive programs permitting zero or reduced cost-sharing on first generic refills:

* We will provide this prescription drug at [insert as appropriate: no **or** a reduced] cost the first time you fill it.]

1. Index of Covered Drugs

Plans must include an alphabetical listing of all drugs included in the formulary that indicates   
the page where members can find coverage information for that drug. Plans may use more than one column for the index listing. The inclusion of this list is required and should start on a separate page.]