Minneapolis Department of Human Services

Medicaid List of Covered Drugs (Formulary) Model Guidelines

Requirements for Medicaid List of Covered Drugs

Effective July 1, 2019

Model Medicaid List of Covered Drugs

Follow these guidelines for the Medicaid List of Covered Drugs:

- Managed care organizations (MCOs) are required to use the most recent version of the standardized Medicaid List of Covered Drugs Guidelines for Families and Children, MinnesotaCare, Minnesota Senior Care Plus (MSC+), and non-integrated SNBC. See Attachment 1, Model Medicaid List of Covered Drugs.
- MCOs must submit their Medicaid List of Covered Drugs for Families and Children, MinnesotaCare, MSC+, and non-integrated SNBC to their DHS contract manager for review and approval.
- Do not combine integrated and non-integrated products into one list of covered drugs document.
- The legend for the Model Medicaid List of Covered Drugs is:
  - Text shown as <text> is required language and may represent variable data
  - Text shown as [text] is optional language, depending on the italicized notes
  - Language in italics is instructions to the MCO. Delete it in the MCO’s version
- MCOs may make modifications as stated in model instructions and approved by DHS.
- MCOs may include the words (toll free) where ever a toll free phone number is listed.
- Whenever a phone number is listed, the TTY must also be provided.
- MCOs can format the document as desired specific to font style, margins and bullets but they must meet contractual and Managed Care Regulation requirements.
- Starting with the Table of Contents through the duration of the document, page numbers need to flow continuously in numeric order.

MCO Medicaid List of Covered Drugs Submission Process

Follow this process to submit the Medicaid List of Covered Drugs to DHS:

- MCO reviews and edits the draft before submitting it to DHS. This includes correcting grammar, spelling and other typographical errors, and ensuring accuracy of data. Errors may cause delays in the approval process.
- Text must be a font size of 12 point or greater. Alternative formats must include large print version, which the Managed Care Regulation defines as font size no smaller than 18 point.
- Submit the following to the DHS contract manager:

Medicaid List of Covered Drugs (Formulary) Model and Guidelines. Effective for July 2019. – FINAL – 01/04/2019
The Medicaid List of Covered Drugs in a format ready for printing
- Report changes to DHS quarterly using the DHS approved State Programs Drug Formulary Change/Update Summary template (if there are no changes from the previous submission, notify the DHS contract manager in writing via email)
- The name and contact information of the person at the MCO to whom questions can be directed
- A Flesch Scale Analysis Readability Score at or below seventh grade level
- A signed attestation that the Medicaid List of Covered Drugs Model and narrative information is accurate as of the date of submission to DHS. The MCO must ensure in their attestation that the MCO has reviewed the information submitted in their list. The narrative information must be accurate and must not contain false or misleading statements. The MCO must have a process to validate that the information provided is correct. This must be signed by an officer within the MCO such as a CEO, CFO or vice president. The officer can delegate a person within the MCO to sign on his or her behalf. The letter of delegation must be on file with DHS.
- Submit revised drafts as necessary until the MCO receives final approval from DHS.
- Send a PDF copy of the final approved version to the DHS contract manager.

Distribution of Final Approved Medicaid List of Covered Drugs Process

MCOs must do the following to get approval of the Medicaid List of Covered Drugs:
- MCOs must post the approved list for all programs to the MCO’s website in machine-readable format. Machine-readable is a format in a standard computer language (not English text) that can be read automatically by a web browser or computer system.
- MCOs must insert a comprehensive written key describing the symbols. For example, an asterisk (*) indicates prior authorization. MCOs must ensure the symbols have appropriate tagging to be read by a screen reader. For example, whenever a caret (^) is used, the screen reader would read “prior authorization” not “Caret.”
- MCOs must comply with contract requirements related to electronic accessibility, including Sections 504 and 508 of the Rehabilitation Act.
- MCOs must provide the list in an alternative format to its members, upon request. Alternative format refers to auxiliary aids and services as defined in the contract and Managed Care Regulation.
- MCOs may provide the list in an alternative format to DHS according to contractual and Managed Care Regulation requirements. (Refer to current contract.)
- MCOs must send a PDF copy of any non-English version of the list to the contract manager and a signed attestation that the non-English version contains the same information as the English version. The MCO must translate the entire list if the MCO translates the list into other languages, except for the list of covered drugs listing (data) area.
• MCOs must send a copy of the approved electronic version of the list in an accessible format for a web environment to the contract manager within two weeks of receiving DHS approval.

Attachment 1: Model Medicaid List of Covered Drugs
ATTACHMENT 1

MODEL Medicaid List of Covered Drugs

[MCO may insert pictures throughout the Medicaid List of Covered Drugs.]

(Cover)

[MCO may insert its plan logo and/or trademark statement on the front and/or back cover as well as inside the Medicaid List of Covered Drugs.]

Medicaid List of Covered Drugs (Formulary) [MCO must add the effective year <YYYY>.]

<Insert name of MCO>

<Insert the names of the programs/products that are covered in this Medicaid List of Covered Drugs.>

<Insert contracted service area by county. Identify program-specific (Families and Children, MinnesotaCare, MSC+, and non-integrated SNBC) counties.>

<Insert name of MCO, address, Member/Customer Service phone numbers including TTY, website (if applicable) and hours of service. This information must be located in a prominent place on the front cover.>

<Insert the month and year (MM/YYYY) of printing. This information is to be included on the front cover. The information included in this list of covered drugs was correct as of < (mm/yyyy).> To see the most current information, <Explain how members can access the most current information.> If you have questions, contact <Member/Customer Services> at the number listed on this page. You can ask for a printed copy of this Medicaid List of Covered Drugs at any time.>

<DHS Approved Date MM/DD/YYYY> The approval date is the date DHS annually approves the wrap language (Example: DHS Approved 01/26/2018).

PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT THE DRUGS WE COVER IN THIS PLAN. Members must use network pharmacies to receive prescription drug benefits.

This list is subject to change and is not all-inclusive. The document is subject to state-specific regulations and rules, including, but not limited to, those regarding generic substitution, controlled substance schedules, preference for brands and mandatory generics whenever applicable. Note to existing members: This list of covered drugs has changed since last year.
Please review this document to make sure that it still has the drugs you take. Please contact <Member/Customer Services> at the number listed on this page with questions.

<If you have Medicare, you need to get most of your prescription drugs through the Medicare Prescription Drug Program (Medicare Part D). You must be enrolled in a Medicare prescription drug plan to get prescription drug benefits.>
Language Block: The language block must be in 18 point font.

Attention. If you need free help interpreting this document, call the above number.

Figure 1 Language Block
Civil Rights Notice

**Discrimination is against the law.** <Insert name of MCO> does not discriminate on the basis of any of the following:

- race
- color
- national origin
- creed
- religion
- sexual orientation
- public assistance status
- age
- disability (including physical or mental impairment)
- sex (including sex stereotypes and gender identity)
- marital status
- political beliefs
- medical condition
- health status
- receipt of health care services
- claims experience
- medical history
- genetic information

**Auxiliary Aids and Services:** <Insert name of MCO> provides auxiliary aids and services, like qualified interpreters or information in accessible formats, free of charge and in a timely manner to ensure an equal opportunity to participate in our health care programs. **Contact** [insert your division’s contact information] [This paragraph must be in 14 size font]

**Language Assistance Services:** <Insert name of MCO> provides translated documents and spoken language interpreting, free of charge and in a timely manner, when language assistance services are necessary to ensure limited English speakers have meaningful access to our information and services. **Contact** [insert your division’s contact information] [This paragraph must be in 14 size font]

**Civil Rights Complaints**
You have the right to file a discrimination complaint if you believe you were treated in a discriminatory way by <Insert name of MCO>. You may contact any of the following four agencies directly to file a discrimination complaint.

**U.S. Department of Health and Human Services’ Office for Civil Rights (OCR)**
You have the right to file a complaint with the OCR, a federal agency, if you believe you have been discriminated against because of any of the following:

- race
- color
- national origin
- age
- disability
- sex
Contact the OCR directly to file a complaint:
Director
U.S. Department of Health and Human Services’ Office for Civil Rights
200 Independence Avenue SW
Room 509F
HHH Building
Washington, DC 20201
800-568-1019 (voice)
800-537-7697 (TDD)
Complaint Portal: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf

Minnesota Department of Human Rights (MDHR)
In Minnesota, you have the right to file a complaint with the MDHR if you believe you have been discriminated against because of any of the following:
- race
- color
- national origin
- religion
- creed
- sex
- sexual orientation
- marital status
- public assistance status
- disability

Contact the MDHR directly to file a complaint:
Minnesota Department of Human Rights
Freeman Building, 625 North Robert Street
St. Paul, MN 55155
651-539-1100 (voice)
800-657-3704 (toll free)
711 or 800-627-3529 (MN Relay)
651-296-9042 (Fax)
Info.MDHR@state.mn.us (email)

Minnesota Department of Human Services (DHS)
You have the right to file a complaint with DHS if you believe you have been discriminated against in our health care programs because of any of the following:
- race
- color
- national origin
- creed
- religion
- sexual orientation
- public assistance status
- age
- disability (including physical or mental impairment)
- sex (including sex stereotypes and gender identity)
- marital status
- political beliefs
- medical condition
- health status
- receipt of health care services
- claims experience
- medical history
- genetic information

Complaints must be in writing and filed within 180 days of the date you discovered the alleged discrimination. The complaint must contain your name and address and describe the discrimination you are complaining about. After we get your complaint, we will review it and notify you in writing about whether we have authority to investigate. If we do, we will investigate the complaint.
DHS will notify you in writing of the investigation’s outcome. You have the right to appeal the outcome if you disagree with the decision. To appeal, you must send a written request to have DHS review the investigation outcome. Be brief and state why you disagree with the decision. Include additional information you think is important.

If you file a complaint in this way, the people who work for the agency named in the complaint cannot retaliate against you. This means they cannot punish you in any way for filing a complaint. Filing a complaint in this way does not stop you from seeking out other legal or administrative actions.

Contact DHS directly to file a discrimination complaint:
Civil Rights Coordinator
Minnesota Department of Human Services
Equal Opportunity and Access Division
P.O. Box 64997
St. Paul, MN 55164-0997
651-451-3040 (voice) or use your preferred relay service

<Insert name of MCO> Complaint Notice

You have the right to file a complaint with <insert name of MCO> if you believe you have been discriminated against because of any of the following:

- medical condition
- health status
- receipt of health care services
- claims experience
- medical history
- genetic information
- disability (including mental or physical impairment)
- marital status
- age
- sex (including sex stereotypes and gender identity)
- sexual orientation
- national origin
- race
- color
- religion
- creed
- public assistance status
- political beliefs

You can file a complaint and ask for help in filing a complaint in person or by mail, phone, fax, or email at:

<Insert name of MCO contact>
<Insert MCO contact title>
<Insert MCO full address>
Toll Free: <Insert MCO toll free phone number> TTY: <Insert MCO TTY toll free phone number> Fax: <Insert MCO fax number>
Email: <Insert MCO contact’s email address>

The American Indian Statement must be in 12 point font.

American Indians: American Indians can continue or begin to use tribal and Indian Health Services (IHS) clinics. We will not require prior approval or impose any conditions for you to get services at these clinics. For elders age 65 years and older, this includes Elderly Waiver (EW)
services accessed through the tribe. If a doctor or other provider in a tribal or IHS clinic refers you to a provider in our network, we will not require you to see your primary care provider prior to the referral.
<Insert a Table of Contents. MCO may alternatively insert the Table of Contents immediately before the list of covered drugs listing.>
What is a list of covered drugs?
A list of covered drugs includes the prescription drugs covered by <MCO NAME>. The drugs on the list are selected by <MCO NAME> with the help of a team of doctors and pharmacists. <MCO NAME> will generally cover the drugs listed in the list of covered drugs as long as the drug is medically necessary, the prescription is filled at a network pharmacy and other requirements related to the drug are followed.

Does the list of covered drugs ever change?
The <MCO NAME> list of covered drugs can change during the course of a calendar year. If changes occur which will impact the coverage of a medication you are taking, <MCO NAME> will make reasonable efforts to contact you and your prescriber to inform you and your prescriber about the change and possible alternative medications which will be covered.

Examples of some changes that may occur are:

- A drug you are taking is no longer preferred.
- A drug is removed from the list of covered drugs due to safety reasons.
- Changes in prior authorization requirements.

How are drugs listed in the list of covered drugs?
<Explain how to find a drug within the list of covered drugs. For example, Medical Condition, Alphabetical Listing.>

What is a Preferred Drug List?
In Minnesota, all managed care organizations are required to follow the Department of Human Services’ Preferred Drug List (PDL). The PDL is created by the Department of Human Services, in consultation with the Drug Formulary Committee, to let prescribers and members know about drugs or drug classes that are more or less cost effective. Generally, drugs that are listed on the PDL as preferred are more cost effective; and drugs that are listed as non-preferred on PDL are less cost effective. Preferred drugs are available to members with fewer restrictions. Non-preferred drugs will require a prior authorization. To receive a non-preferred drug, your doctor or health care provider must get prior authorization. The Preferred Drug List is a portion of your <MCO NAME>’s list of covered drugs. <MCO NAME>’s list of covered drugs is a complete list of all covered drugs. The Preferred Drug List is available on the department’s website: Minnesota Fee-for-Service Medicaid Preferred Drug List (mn.gov/dhs/mhcp/ffs-preferred-drug-list).

What are generic or biosimilar drugs?
A generic drug is approved by the Food and Drug Administration (FDA) and has the same active ingredient as the brand-name drug and produces the same clinical effect as the brand-name drug.
A biosimilar drug is an FDA-approved biologic drug (most often an injectable prescription drug) that is highly similar to and has no clinically meaningful differences in terms of safety and effectiveness from an already-approved biological product. Biosimilar drugs are not the same as generic drugs, but like generics, biosimilar drugs may offer more affordable treatment options for you.

Generic or biosimilar substitution means a generic version or biosimilar version of a drug is given instead of the brand name or non-biosimilar version of the drug.

<MCO NAME> will cover the brand name or non-biosimilar version of the drug only when:
1. Your prescriber informs <MCO NAME> in writing that the brand name or non-biosimilar version of the drug is medically necessary; OR
2. <MCO NAME> may prefer the dispensing of certain brand-name version over the generic or non-biosimilar version over the biosimilar version of the drug; OR
3. Minnesota law requires the dispensing of the brand-name or non-biosimilar version of the drug.

Within the list of covered drugs, brand-name drugs are [Explain how brand-name drugs are identified. For example, listed in capital letters] and generic drugs are [Explain how generic drugs are identified. For example, listed in lower case letters.]

What are over-the-counter drugs?
Drugs and products that are available for purchase without a prescription are referred to as over-the-counter (OTC). Although an OTC product is available without a prescription, if a doctor writes a prescription for an OTC product, <MCO NAME> may cover it.

What are specialty drugs?
Specialty drugs are used by people with complex or chronic diseases. These drugs often require special handling, dispensing or monitoring by a specially-trained pharmacist.

If an MCO uses an exclusive Specialty Drug Provider, use this language:
If you are prescribed a drug that is on the <MCO NAME> Specialty Drug List, your prescriber will need to send the prescription of that specialty drug to <MCO NAME>’s specialty pharmacy.

Name of Specialty Pharmacy:
Phone and TTY:
Fax:
Hours of Operation:
You will also need to call the specialty pharmacy at <insert phone number> to set up an account. You will need to have your <MCO NAME> member identification (ID) card when you call the specialty pharmacy.

If an MCO uses multiple Specialty Drug providers, use this language:

If you are prescribed a drug that is on the <MCO NAME> Specialty Drug List, your prescriber will need to send the prescription of that specialty drug to one of <MCO NAME>’s specialty pharmacies listed here.

Name of Specialty Pharmacy:
Phone and TTY:
Fax:
Hours of Operation:

You will also need to call the specialty pharmacy that receives your prescription to set up an account. You will need to have your <MCO NAME> member ID card when you call the specialty pharmacy.

What if a drug is not on the list of covered drugs?
Not all drugs are covered. If a drug is not listed in the list of covered drugs, you should contact <Member/Customer Services> at <Insert phone number including TTY> and ask if the drug is covered. If not, it is considered a non-formulary drug. If you need a drug that is not included in the list of covered drugs, [Explain how members can request a drug that is not on the list of covered drugs.]

Are there any restrictions on my coverage?
Some covered drugs may have additional requirements or limits on coverage. These requirements and limits may include:

● **Prior authorization:** <MCO NAME> requires you or your <doctor or health care provider> to get prior authorization for certain drugs. This means that you will need to get approval from <MCO NAME> before you fill your prescriptions. If you don’t get approval, <MCO NAME> may not cover the drug.

● **Quantity limits:** For certain drugs, <MCO NAME> limits the amount of the drug that <MCO NAME> will cover.

● **Age requirements:** In some cases, there are age requirements for you to try certain drugs. A prior authorization is needed depending on your age and the specific drug prescribed.
You can find out if your drug requires prior authorization, has quantity limits, or has an age requirement by looking in this list of covered drugs. A drug restriction or limit can be removed if your doctor submits a statement or documentation supporting the request. Refer to your Member Handbook for more information. You can also get more information about the restrictions applied to specific covered drugs by contacting <Member/Customer Services> at <Insert phone number including TTY> or by visiting our website at <MCO Website>.

- **Excluded drugs:** Some drugs are excluded from the list of covered drugs. Excluded drugs include the following:
  - Drugs used to treat sexual or erectile dysfunction
  - Drugs used to enhance fertility
  - Drugs used for cosmetic purposes, including drugs to treat hair loss
  - Drugs or products to promote weight loss
  - Drugs not clinically proven to be effective
  - Investigational or experimental drugs
  - Medical cannabis

**Can I request an exception to the coverage restrictions?**
Yes. Your healthcare provider can obtain the <Name of Form> from <MCO Website> or by contacting, <Member/Customer Services> at <Insert phone number including TTY>. Your provider must return this form to the fax number or address listed on the document. To facilitate a thorough review and to ensure that your healthcare provider receives a response within 24 hours, <MCO NAME> asks that all information requested in the form be provided, including documentation of which medications have been tried and failed, including the dosages used, and the identified reason for failure (e.g. side effects).

**What will a prescription cost?**
All copay information for prescriptions is listed in the Member Handbook. If you have additional questions, contact <Member/Customer Services> at <Insert phone number including TTY> or by visiting our website at <MCO Website>.
<List of Covered Drugs>

MCO may insert a comprehensive written key prior to the List of Covered Drugs listing.
(Back Cover)

[MCO may insert its plan logo and/or trademark statement and plan contact information.]