SECTION VIII: PHARMACY

OVERVIEW OF PHARMACY PROGRAM

Medicare Part D covers prescription drugs for persons that are Medicare eligible. Neither Medicare Part A (Hospital Coverage) nor Medicare Part B (Physicians Office Coverage) covers most outpatient prescription drugs.

The Medicare Modernization Act (MMA) provides the rules that govern coverage under Part D. These rules are:

- The drug must be approved by the Food and Drug Administration (FDA)
- The drug must be used and sold in the United States
- The drug is available by prescription
- The drug is used for medically accepted indications

A Part D drug includes prescription drugs, biological products, insulin, and medical supplies associated with injection of insulin. As per regulation, the supplies associated with insulin injection include syringes, needles, alcohol swabs, and gauze.

Part D coverage also requires that the drug be used for medically accepted indications. Medically accepted indications are defined by statute under the Part D benefit. This definition includes:

- FDA approved indications
- Drugs listed as safe and effective for a specific use in one of four drug compendia[1]

Based on this statutory definition, indications supported in peer-reviewed literature or practice guidelines are not medically accepted unless they appear in one of the compendium. Therefore, the use of a drug for indications outside the FDA labeling and compendia does not meet the definition of a Part D drug and payment is not allowed.

In addition to the drugs that are covered under Part D, the regulation also specifies which drugs are excluded. The definition of an excluded drug includes any drug that is covered under either Medicare Part A or Medicare Part B.

The exclusions for Medicare Part D are drugs that are also excluded from Medicaid coverage, with the exception of smoking cessation. The drugs or classes that are currently restricted are:

[1] These include: American Hospital Formulary Service Drug Information (AHFS); United States Pharmacopeia-Drug Information (USP-DI); DRUGDEX Information System; American Medical Association Drug Evaluations (no longer available)

- Agents used for weight loss
- Agents used for weight gain (including cancer and HIV)
- Agents used to promote fertility
- Agents used for cosmetic purposes
- Agents that promote hair growth
- Agents used for symptomatic relief of cough and colds
- Prescription vitamins and mineral products (except prenatal vitamins and fluoride preparations)
- Nonprescription drugs (OTC drugs)
- Outpatient drugs where the manufacturer requires associated tests or monitoring services be purchased from the manufacturer or its designee as a condition of sale
- Barbiturates
- Benzodiazepines

There are 13 categories of drugs for which separate payment is made under Medicare Part B[2]. These drugs include:

- Drugs furnished incident to a physician's service
- Separately billable end stage renal disease drugs in patients undergoing dialysis
- Osteoporosis drugs provided by home health agencies under certain conditions
- Drugs used in immunosuppressive therapy for a transplant covered under Medicare
- Parenteral nutrition for individuals with a nonfunctioning digestive tract
- Infusable Durable Medical Equipment (DME) supply drugs
- Intravenous immune globulin (IVIG) provided in the home for individuals with a diagnosis of primary immune deficiency
- Certain oral chemotherapy agents used in cancer treatment for which there is an infusible version of the drug and have a medically accepted indication
- Oral anti-emetics used in cancer treatment as a FULL replacement for intravenous treatment
- Hepatitis B vaccine for individuals at high or intermediate risk of contracting hepatitis B
- Inhalation DME supply drugs when a nebulizer has been provided by Medicare

[2] It is important to note that if a drug is determined to be a Part B drug, but the individual does not have Part B coverage, the drug may **not** be billed through Part D instead.

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Medication Therapy Management (MTM) Program

The Medication Therapy Management (MTM) Program ensures optimum therapeutic outcomes for targeted beneficiaries (multiple chronic medical conditions, taking many prescription medications, minimum medication cost threshold) through improved medication use. The goal of the program is to reduce the risk of adverse events, including adverse drug interactions and improve the quality and cost effectiveness of the pharmacy benefit. The ONECare MTM program is offered at no additional cost. By assisting in the reduction of both over and underutilization, this program helps us make sure that our Members are using the appropriate drugs to treat their medical conditions and to identify possible medication problems. This is a voluntary program. This program is administered by SinfoniaRx.

Pharmaceutical Quality Assurance

ONECare established measures and systems to conduct drug utilization reviews for all of our Members to make sure that they are getting safe and appropriate care. The programs include real-time and historic review of prescriptions claims to reduce medications errors and adverse drug interactions. These reviews are especially important for Members who have more than one doctor who prescribe their medications, use more than one drug, or have more than one pharmacy.

ONECare conducts drug utilization reviews when the pharmacy fills a prescription at the point-of-sale. The claim may be electronically reviewed for the following:

- Screen for duplicate drugs that are unnecessary because Member is taking another drug to treat the same medical condition.
- Age-related contraindications
- Gender-related contraindications
- Drug-Drug interactions
- Incorrect drug dosage
- Drug-Disease contraindications
- Drug-Pregnancy precautions
- Clinical abuse or misuse

In addition, retrospective drug utilization reviews identify inappropriate or medically unnecessary care. We perform ongoing, periodic review of claims data to evaluate prescribing patterns and drug utilization that may suggest potentially inappropriate use.

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Pharmaceutical Utilization Management

This program incorporates utilization management tools to encourage appropriate and cost-effective use of Part D medications. The ONECare Pharmacy & Therapeutics Committee developed these requirements and limits to help us provide quality coverage to our Members. These tools include, but are not limited to: prior authorization, clinical edits, quantity limits and step therapy.

- Age Limits: Some drugs may require a prior authorization if the patient's age does not meet the manufacturer, FDA, and clinical practice guidelines.
- Quantity Limits: For certain drugs, we limit the amount of the drug we cover per prescription or for a defined period of time. Similar to the age limit, the quantity limit threshold is based on manufacturer, FDA, and clinical practice guidelines.
- Prior Authorization: Prior authorization is required for certain drugs. Typically, a prior authorization is established to ensure appropriate utilization.
- Step Therapy: In some cases, ONECare requires that the patient has a trial of a first-line medication, prior to approving a second-line medication.
- Generic Substitution: When there is a generic version of a brand-name drug available, our network pharmacies automatically dispense the generic version, unless the prescription indicates "brand only". If an FDA-approved generic alternative is available on the ONECare formulary, the prescribing physician must submit medical justification for the use of the brand product.

The ONECare formulary is available on the ONECare website (www.care1st.com/az). ONECare Members shall have access to all FDA-approved drugs that are medically necessary via the drug formulary or prior authorization procedures. In order to ensure Members receive high quality, cost-effective and appropriate drug therapy, ONECare maintains drug formularies consistent with the required pharmacy benefit design for all contracted product lines. The formularies are maintained by the ONECare Pharmacy & Therapeutics (P&T) Committee.

Prior Authorizations

The ONECare Pharmacy Department ensures a timely and accurate review of all medication authorization requests. Prior authorization requests are determined 72 hours after receipt of complete information from the provider for Standard determinations. Expedited reviews are determined within 24 hours after receipt of complete information from the provider. ONECare shall provide an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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Medication authorization requests may be submitted by the member, member's representative, member's prescribing physician, or other physicians.

Medications requiring authorization include (but are not limited to):

- Medications on the ONECare formularies requiring a prior authorization (PA) review
- Non-formulary medications
- Part B versus Part D determinations

The ONECare Pharmacy Department provides written communication of the prior authorization determination to the Member and provider.

Definitions

"***Approved***" – ONECare agrees to cover the requested medication.
"***Denied***" – The medication request is not approved.
"***Non-formulary***" – A medication not listed on the ONECare formulary.
"***PA Required***" – A medication on the ONECare formulary that requires P.A. review.
"***Specialty Pharmaceutical***" – Defined by the criteria included in AB2420.

Procedure

1. Most medications on the ONECare drug formulary do not require prior authorization. The Member simply obtains a prescription from his/her provider and has it filled at a participating pharmacy.
2. The P&T Committee may require PA for certain medications in order to promote appropriate use. Products designated as requiring PA are not covered unless approved in advance for a specific patient, product and length of therapy
3. The P&T Committee reviews and approves the medications included in the ONECare formularies on an ongoing basis to ensure that the formularies are clinically appropriate and consistent with current pharmaceutical treatment guidelines. In a situation where the provider identifies a need for the Member to receive a medication not on the ONECare formularies, he/she may submit a request by completing the ONECare Medication Prior Authorization Form.
4. The prescriber or prescriber's staff, may make an exception request based on medical necessity by submitting a PA request by telephone, fax, or the ONECare website to the ONECare Pharmacy Department. The member may also make an exception request by calling member services, at which point the ONECare Pharmacy Department initiates a prior authorization request. The ONECare formularies identify the medications requiring PA Providers may not utilize a third party agent to assist with the preparation of a medication PA Third party agents may not submit PA requests on behalf of the provider.
5. The ONECare Pharmacy Department captures the date and time of the PA request by the fax received stamp on the PA form. If a provider telephones in the request the ONECare Pharmacy staff completes the request and document the date and time received in the Pharmacy PA database.

6. The request is reviewed pursuant to the P&T Committee's approved PA guidelines to ensure the safe, efficacious, appropriate and cost-effective use of the medication.
7. If a Member presents a prescription at a retail pharmacy requiring a PA that has not been processed, the pharmacy contacts the prescribing practitioner and requests a therapeutic substitution. The pharmacy staff may contact the ONECare Pharmacy Department for assistance with the identification of formulary alternatives.
8. If the practitioner does not agree to the substitution, the retail pharmacy informs the prescriber that he/she may contact the ONECare Pharmacy Department.
9. Once contacted, the ONECare Pharmacy staff initiates the process for obtaining medical necessity information from prescribing practitioners. In most circumstances, this is done via fax on a standardized form. Due to the need for timeliness, it may be necessary to discuss the request telephonically with the prescribing practitioner:
    a. The ONECare Pharmacy staff reviews the request against a written protocol which the P&T Committee has approved. If the PA information submitted does not meet the criteria outlined in the PA guidelines, it is forwarded to the ONECare clinical pharmacist.
    b. The clinical pharmacist reviews the request and may consider it appropriate as requested, or may determine another formulary medication may be a reasonable therapeutic substitution.
    c. If the request is medically appropriate an override is entered in the pharmacy benefit manager's (PBM) system so the medication can be processed.
    d. If there is a formulary alternative available the clinical pharmacist advises the ONECare Pharmacy staff in providing the appropriate communication to the provider. For medications requiring immediate attention, the clinical pharmacist contacts the provider directly. For non-urgent medication requests, the suggestion of an alternate formulary agent may be communicated by written notification
    e. If the clinical pharmacist determines the need for additional medical information he/she provides written documentation requesting that the ONECare Pharmacy staff assist in requesting the necessary data.
    f. The Pharmacy staff documents the date and time for each request submitted to the provider's office. This includes requests for routine PA information and additional information as authorized.
    g. The Pharmacy staff solicits a response from the physician's office daily for three (3) consecutive business days. The request for information is sent by facsimile. If the request for information is made verbally, this action is documented in the ONECare PA database.
    h. If the required information is not obtained by the third business day from receipt of the initial PA request, a request for additional information letter is sent to the member providing notice that ONECare is unable to render a determination due to the fact that the required information has not been submitted to ONECare. The PA request is placed in a deferred or pended status and remain active for fourteen (14) calendar days, upon which ONECare provides written notice informing the member that the required information is still outstanding and the request cannot be approved due to the lack of information submitted. If the required information is submitted prior to the expiration of the fourteen (14) calendar day period the

PA request is reviewed by the Clinical Pharmacist and Chief Medical Officer or designated physician reviewer, and a decision is rendered within one (1) business day of receipt of complete information. If the required information is submitted after the fourteen (14) calendar day period, the PA review process is reinstated.

10. If the clinical pharmacist cannot approve the medication, the PA request along with all applicable information is forwarded to the ONECare CMO or designated physician reviewer.
11. The CMO or designated physician reviewer reviews all deferred cases for medical appropriateness and to identify opportunities to educate providers.
12. All PA denials are determined by the ONECare Chief Medical Officer or designated physician reviewer except administrative denials to include but not limited to denials due to member's non-eligibility with ONECare Health Plan or due to carve out medications, which can be denied by the reviewing pharmacist. If a PA request is denied, a denial letter is sent by the Pharmacy Department to the member within one business day of the determination. In addition, a copy of the denial letter is faxed to the prescribing physician or PCP. The notification includes the following elements:
    a. A clear and concise explanation of the reason for the denial or modification.
    b. For denials of medications based on the absence of a trial or failure of formulary agents, ONECare provides a list of the potentially applicable formulary agents.
    c. Criteria, clinical guidelines or medical policies used in reaching the determination.
    d. Information regarding the member's right to appeal the decision and the steps for submitting either a standard or expedited grievance.
    e. The ONECare toll-free phone number and address for submitting grievances.
    f. For denials based on the fact that the requested service is not a covered benefit, the notification identifies the document and page where the provision is found and provide a clear concise explanation of the application of the exclusion to the service requested.
13. Additionally, the information regarding the denial/modification including the Member outcome is logged into the pharmacy database system. When the decision is made and sent out to the provider, Member or pharmacy, it is dated and time stamped to comply with the turn-around-time requirement for processing. Turn-around-time measurements are based on the date and time of receipt of all information necessary to make an informed clinical determination.
14. If a PA request is approved, the prescriber or PCP receives a faxed override letter as notice of the approval. The override letter informs the physician of the date and term of the approval.
15. If a PA request from the prescriber or PCP is modified, the prescriber or PCP receives, within one business day, an information notice of the modification. However, if the PA request was initiated by the member, a denial notice is provided to the prescriber/PCP. The member also receives the denial notice informing him/her of the modification to a formulary alternative medication by the physician.
16. If a PA approval is required for coverage of an antibiotic or life-sustaining medication (other than excluded products), an emergency supply is covered under the following

circumstances if the outlined procedure is followed (even if a subsequent formal application for PA is denied):

a. A pharmacist receives the prescription and attempts, but is unable, to contact the prescriber to prompt a request for a PA medical necessity approval or prescription change to a product not requiring such approval for coverage,
b. If the pharmacist telephones or faxes ONECare and is unable to get through due to technical difficulties during ONECare's normal business hours.
c. If the pharmacist determines the situation warrants it the pharmacist dispenses an emergency supply of the product, usually a 72-hour supply (although up to a four- or five-day supply may be dispensed under extenuating circumstances, e.g., a Friday evening or holiday weekend).
d. On the following business day the pharmacist contacts the ONECare Pharmacy Department providing the Member's demographic information, the medication dispensed (including the amount and strength), the prescriber's name and office phone number, and the circumstances of the emergency.
e. The pharmacist contacts the prescriber regarding the need to apply for the required PA approval or to change the prescription to a product not requiring approval for coverage.

17. Routine Pharmacy Denial Activity reports are submitted to the P&T Committee for review.

Member Coverage Determination, Exceptions, and Appeals

ONECare follows the policy and procedures set forth in the ONECare Beneficiary Coverage Determination, Exceptions (Prior Authorization) P&P to administer and comply with the Medicare Part D requirements for performing these functions.

Providers may access the Pharmacy Prior Authorization request on the ONECare website (www.care1st.com/az) or by calling the ONECare Pharmacy Department. Verbal requests are accepted from medical providers.