

## **20 PHARMACY**

Revision dates:

Effective dates: January 1, 2019

### **GENERAL INFORMATION**

#### **Pharmacy Benefits: Centennial Care Programs**

Prescription drugs are a benefit under the Centennial Care program to be covered by the Managed Care Organizations (MCOs). MCOs shall support HSD in promptly responding to public and legislative inquiries involving the design and management of the MCO's pharmacy benefit.

#### **Preferred Drug List and Formulary Requirements**

MCOs shall maintain a distinct formulary or preferred drug list (PDL) for Centennial Care including all multi-source generic drug items with the exception of cosmetic items, fertility drugs, anti-obesity, items not medically necessary, and cough, cold and allergy medications. This requirement does not preclude MCOs from requiring a prior authorization for a multi-source generic item. In establishing the formulary, MCOs shall ensure that the prescription drug benefit covers at least the same level of services as the base benchmark pharmacy benefit, including one drug in every category and class or the number of drugs covered in each category and class as the base benchmark, whichever is greater.

The formulary or PDL must also contain brand name drugs as necessary including sole source brand name drugs.

The formulary or PDL can never be considered absolute. A prescribing practitioner must always have the ability to request a non-formulary or non-PDL drug item using a prior authorization a request. The MCO must then evaluate the request for medical necessity. A denial of the request is subject to an MCO member appeal that may extend to an HSD administrative hearing.,

For drugs requiring prior authorization, the MCO must accept the Uniform Drug Authorization Request Form (See attached MAD 635) as stated in 4.12.10.1.6.

MCOs shall have an open formulary for all Psychotropic Drugs and Medications. Psychotropic medications include all drugs whose primary purpose is to treat behavior health conditions. Not included in this definition are "central nervous system stimulants" such as items used to treat attention deficit disorders, or minor tranquilizers used to treat simple anxiety such as diazepam and chlorthalidone.

Prior authorization is not required to dispense a brand name drug rather than a generic equivalent is for prescriber certified "Brand Medically Necessary" prescriptions and neither a demonstration of fail first, nor step therapy, on the generic item will be required prior to dispensing the brand name drug when the prescriber has certified "Brand Medically Necessary."

#### **Treatment Guidance for Chronic Hepatitis C Virus (HCV) Infection**

MCOs shall establish a system to cover treatment of members over the age of 17 years old with active Hepatitis C infection for a minimum of three (3) months, consisting of:

- The approval process of properly requested treatments for members with chronic HCV infection using the Uniform New Mexico HCV Checklist for Centennial Care (See MAD 634 Attached);
- The development of a provider incentive plan to expand the number of practitioners treating HCV in New Mexico, including:
  - a. Incentive(s) to receive training in the treatment of chronic HCV infection;
  - b. Incentive(s) to begin treating such patients; and
  - c. Incentives for treatment of each patient;
- Not using active alcohol or drug use screening criteria for the treatment, approval or denial process;
- Not using the specialty of the requesting provider as screening criteria for treatment, approval or denial;
- Referral of all members to a community health worker, care coordinator, or MCO specialty pharmacist at the time of a drug treatment request for guidance and treatment compliance;
- Quarterly data submission concerning number of requests, approvals, and denials by fibrosis stage (or equivalent) and genotype for all treatment requests;
- Sending a representative to attend quarterly meetings with other MCOs and MAD representatives as part of the ongoing HCV workgroup to review current data and recent guidance revisions and propose evidence-based future revisions to treatment guidelines;
- A comprehensive plan of outreach to the MCOs' referring providers requesting oral drug treatment for chronic HCV-infected patients;
- A comprehensive plan to expand HCV case finding efforts and screening efforts; and
- A comprehensive plan to expand HCV screening efforts to conform to USPSTF/CDC/AASLD/IDSA guidelines.

MCOs are to approve properly requested treatments for the following Centennial Care members with chronic HCV infection:

1. All members over age 17, all HCV genotypes, with a positive Hepatitis C RNA level;
2. In all cases, the MCOs shall ensure (using the AASLD/IDSA guidelines) that each treatment request is appropriate with respect to:
  - a. HCV genotype and viral load;
  - b. Drug dose(s) and duration(s). Note that the MCOs' preferred formulary agent may be given preference if the level of evidence and effectiveness (as measured by SVR) is equal or greater, and no drug interactions are of concern;
  - c. The presence or absence of advanced fibrosis or cirrhosis. For the purpose of making treatment decisions using the AASLD/IDSA guidance, "cirrhosis" can be considered to be present if any of the following are present:
    - i. APRI  $\geq$  1.01;
    - ii. Fib-4  $\geq$  3.252;
    - iii. Transient Elastography Score  $\geq$  12.5 kP<sup>3</sup> (F4 equivalent);
    - iv. Fibrotest  $\geq$  0.73<sup>4</sup> (F4 equivalent) OR Fibrometer with F4

- predominance;
    - v. Radiographic imaging or physical exam findings consistent with cirrhosis; and
    - vi. Liver biopsy confirming a METAVIR Score of F4;
  - d. Prior HCV treatment experience.
    - i. Plans may require resistance-associated substitutions (RASs) testing, based on AASLD guidance.
- 3. Guidance regarding lost or stolen medications:
  - a. MCOs shall use the same criteria currently used for refills of other lost or stolen medications; and
  - b. MCOs shall use Care Coordination and other functions to minimize this occurrence.
- 4. Guidance regarding requests for off-label, experimental, and other forms of treatment that are not specified in the guidelines:
  - a. MCOs shall initiate a peer to peer consultation with the requesting physician to further understand the request and its rationale; and
  - b. MCOs shall present the case to Project ECHO before issuing a denial.
- 5. Note that a "properly requested treatment" as defined above means that:
  - a. The checklist form is completed fully as directed and submitted;
  - b. Necessary lab data and copies of medical records are attached; and
  - c. The requested drug(s), dose(s), and length of treatment are consistent with AASLD/IDSA guidance as written (the level of evidence in the guidance should not be considered relevant to length of treatment decisions). If not consistent, MCOs shall provide an appropriate alternative.
- 6. MCOs are granted the option to expand their treatment criteria beyond these guidelines (e.g., to those 17 years of age and under), with advance notice to and approval by the Medical Assistance Division.

### **Community Pharmacy Reimbursement**

1. MCOs shall ensure that reimbursement to Community-Based Pharmacies realistically reflect buying power, buying volume, and price negotiating potential. MCOs must ensure that the Maximum Allowed Cost (MAC) for ingredient cost generic drugs for Community-based Pharmacies is no lower than the current National Average Drug Acquisition Cost (NADAC) listed for the National Drug Code (NDC) for the drug item. The dispensing fees will be paid in accordance with the terms of the applicable pharmacies' contracts.

Where there is not a NADAC price available, such as for certain over-the-counter (OTC) drug items, certain generic drugs that have few manufacturers, and some repackage products, the MAC must be no lower than the published Wholesaler's Average Cost (WAC) listed for the NDC plus 6%. The WAC must come from a published national pharmacy pricing source such as Medispan or First Data Bank that is not associated with

the MCO or PBM. This pricing methodology for certain OTC drug items aligns with the state's reimbursement structure under Medicaid fee-for-service (FFS). Such pricing is in effect only for drug items that do not have a NADAC price available.

If the pharmacy submits an ingredient cost less than NADAC (or the WAC plus 6% when applicable), then the MCO's PBM may use that lower submitted amount as the ingredient cost.

- a. A Community-Based Pharmacy is a pharmacy that has the following characteristics:
  - Is open to the public for prescriptions to be filled, regardless of the facility or practice where the prescription was written. This includes multi-site pharmacy operations and franchises whose locations are in New Mexico;
  - Is located in New Mexico or near the state border, if the border town is a primary source of prescription drugs for Centennial Care members residing in the border area;
  - Is not government-owned, not hospital-owned or hospital-based, not an extension of a hospital, not owned by a corporation owning hospitals, and not an extension of a medical practice or specialty facility;
  - Is not owned by a corporate chain with stores outside of New Mexico;
  - Is not a mail order pharmacy; and
  - Is not part of a national network of pharmacies or specialty pharmacies, including those primarily used for supplying IV admixtures.

- b. A list of pharmacies to which this section of this policy applies is included at the end of this policy. HSD develops and maintains the criteria for inclusion on the list and applies only to community based pharmacies that participate in the MCOs' Centennial care network. Inclusion of a pharmacy on the list does not mandate inclusion of the pharmacy in the MCOs' Centennial Care network. This does not supersede any credentialing requirements established by the MCO or its Pharmacy Benefit Manager (PBM). Pharmacies on the list that are not contracted for participation in the MCOs' Centennial Care network will be subject to the MCOs' out-of-network payment rules.

- d. The MCO is not obligated to adjust claims retroactively based on changes made by HSD/MAD to the list.

## 2. Calculation of Payment:

- a. A pharmacy cannot be required to submit a dispensing fee on the claim, nor shall the payer use a submitted dispensing fee to limit payment. MCOs must ensure that the contracted dispensing fee is used in the payment calculations; and

- b. MCOs must pay the Administration fee, compounding or assembling fee, consultation fee, and/or prescribing fee when specifically established by Mad, such may be done for Naloxone and oral contraceptives. Currently, these add-on payments apply primarily to injections and Naloxone kits.

3. Updating Prices:

- a. NADAC prices (or WAC prices plus 6% for OTC drug items) must be implemented within seven (7) calendar days of NADAC price changes. If a price increase is not made within 7 calendar days, MCOs must ensure that pharmacy claims are adjusted to reflect the price increase for claims that were not paid at the increased price. A price decrease cannot be implemented retroactively;
  - b. For MAC prices determined by an MCO (other than NADAC and WAC plus 6%), the MCO must ensure that all MAC payment levels are reviewed, at a minimum, once per week. If there is a price increase that took place during the week that resets the MAC price, an increase must be implemented within seven (7) calendar days. If a price increase is not made within seven (7) calendar days, the MCO must ensure that paid pharmacy claims are adjusted to reflect the price increase, if they were not paid at the increased price. A price decrease cannot be implemented retroactively; and
  - c. MAC prices must be established by evaluation a range of prices from sources with prices available in New Mexico. Documentation must be retained on how the price was selected and how it was determined that the price was available in New Mexico. If an MCO selects the lowest price available, documentation must be maintained showing that the source of the MAC price is available from wholesalers in New Mexico. Short-term, special deal prices cannot be used to set a MAC price at the lowest available price.
4. MCOs must cover flu shots, including the booster-enhanced flu shots for members when prescribed for recipients 65 and older and for other conditions per CDC seasonal recommendations.
5. MCOs must follow MAD direction regarding the minimum amount of information that must be reported back to the pharmacy on a price challenge. When a MAC price challenge is made on the basis of failing to update a price within the applicable timeframes, and a pharmacy "wins" the challenge, MCOs must ensure that all pharmacy claims that were underpaid, due to the lack of a timely update, are adjusted.

MCOs must require that if the pharmacy does not "win" the challenge, that the response to the pharmacy shall state: (1) the drug price that is in effect on the date of service; (2) the date that the price was established as the MAC price; (3) if the MAC price has

subsequently changed since the date of the prescription and the current MAC price; (4) the basis of that price; that is, how the price was established; (5) the NDC if the price is based on specific NDC; and (6) how they concluded the price was available in New Mexico.

6. MCOs must accept the price challenges directly from the pharmacy if the MCO's PBM is setting the price unless the pharmacy contract with the PSAO requires challenges to go through the PSAO, in which case the MCO must require the PSAO to forward challenges to the MCO within 3 business days of receipt from the pharmacy, and require the PSAO to forward any response to the pharmacy within 3 business days of receipt from the MCO.
7. For a claim recoupment or payment reduction made more than seven (7) calendar days after initial payment, a provider must be notified about the reason for the recoupment or reduction, the amount of the recoupment or reduction, and given an opportunity to appeal or file a grievance. There is not a fair hearing right. This requirement does not apply if the pharmacy is reversing or rebilling the claim that results in a recoupment or payment reduction.

If the pharmacy contract with the PSAO requires that notice of payment recoupment or reduction go through the PSAO, the MCO must require the PSAO to forward such notices including language regarding the opportunity to appeal the pharmacy within three (3) business days of receipt from the MCO and the PSAO to forward any response to the MCO within three (3) business days of receipt from the pharmacy.

### **MCO Participation in the Drug Utilization Review (DUR) Board and Submission of a DUR Annual Report**

MCOs shall take part in a DUR program that complies with the requirements set forth in 42 C.F.R. § 438.3(s) and 42 C.F.R. Part 456 Subpart K, and Section 1927(g) of the Social Security Act, to assure that prescriptions are appropriate, medically necessary, and minimize the potential for adverse medical results. MCO representation on the DUR Board shall consist of one physician and one or two pharmacists.

#### **DUR Reporting Requirements:**

MCOs are contractually responsible for providing outpatient drug benefits and for conducting utilization review activities to promote the delivery of quality medically necessary care in a cost effective and programmatically responsible manner. To ensure all areas of section 1927(g) of the Act are met, MCOs must provide a detailed description of their DUR program activities to the State on an annual basis.

MCOs are required to take part in a Drug Utilization Review (DUR) program and as part of this program, per CMS requirements, each MCO will be required to submit a DUR report to HSD that will be submitted to CMS. The report template is provided by CMS and at minimum shall contain the following:

1. A description of the nature and scope of the prospective and retrospective drug review Program;
2. Detailed information on the specific criteria and standards in use;

3. A summary of the educational interventions used and an assessment of the effect of these
4. interventions on the quality of care; and
5. An estimate of the cost savings generated as the result of the program.

For your reference, the following are links to the CMS website for previous DUR reports:

All States: <https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/annual-reports/index.html>

New Mexico: [https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/2016\\_NM\\_DUR.pdf](https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/2016_NM_DUR.pdf)

### **MCO requirements regarding the Drug Rebate Analysis and Management System (DRAMS) and drug rebate dispute resolution**

HSD's PBM will continue to send drug rebate invoices to manufacturers based on the encounter data for pharmacy and medical claims submitted by the MCOs. HSD's PBM will receive copies of the manufacturers' checks. If the manufacturer does not pay the invoice in full because the manufacturer disputes some of the data on the invoice, HSD's PBM will refer the manufacturer dispute to the appropriate MCO staff.

Typically, when the manufacturer disputes the invoice based on incorrect data on the claims, the manufacturer will request claim level detail (CLD). HSD's PBM will send the claim level detail to the manufacturer.

After the manufacturer reviews the CLD, the manufacturer may issue a dispute in the form of an email or letter, and request that the payer review the claims.

When a dispute is reported to the MCO, the MCO is responsible for reviewing their pharmacy claims data to determine if the data needs to be corrected or if the data is correct. This entails reviewing claims and possibly contacting pharmacy and medical providers to obtain information to resolve the dispute. The MCO must report the resolution of the dispute to HSD's PBM within 30 calendar days from the date of receiving the notice of the dispute.

A smaller number of disputes are initiated after the manufacturer has already paid the invoice. These disputes will be handled in the same manner as other disputes.

HSD's PBM will review the MCO pharmacy and medical drug claims data prior to printing invoices in an attempt to minimize disputes. Often, for specific drug items, reporting the correct number of units is a common problem and the correction may be obvious to HSD's PBM. In such cases it will make the change prior to printing invoices. Usually, the problem occurs when the standard billing units differ from the units that CMS expects to be used on the rebate invoices. A problem also may occur when an MCO allows a provider to bill incorrect units. HSD's PBM will notify an MCO of any situation where the MCO continues to make the same error in data and the MCO will be required to implement corrections in their processing of claims.

## COMMON DISPUTE REASONS

Disputes frequently result from recurring circumstances and often for the same drug items each quarter. When the error that will likely lead to a dispute originates with the provider and the MCO does not detect the error when processing the claim, the MCO will be asked to correct their claims processing editing to avoid continual disputes.

The following sections identify the most common reasons for disputes.

### 1. Unit Type Discrepancy

A provider bills a claim utilizing a unit type that differs from the unit type that was utilized in calculating the rebate. Most claims processing systems allow providers to utilize only three (3) unit types when billing claims. CMS has eight (8) unit types for claims.

#### Common Claim Processing System Unit Types

- Each (caps, tabs, kits, and vials)
- Milliliters (liquids)
- Grams (solids)

#### CMS Unit Types

- AHF (refers only to injectable Anti-Hemophilic Factor units)
- CAP (capsule)
- SUP (suppository)
- GM (grams)
- ML (milliliter)
- TAB (tablet)
- TDP (transdermal patch)
- EA (each, refer to drugs not identifiable by any other unit type as given in program instructions)

Staff of HSD's PBM will convert the common claims processing unit types before preparing manufacturer invoices. If a dispute occurs based on unit conversion or for units that were not converted, HSD's PBM will make the correction in order to resolve the dispute.

If the unit type appears to be incorrect on the original encounter claim, the dispute will be sent to the MCO DRAMS contact for resolution.

### 2. Data Entry Errors Regarding the Quantity

Incorrect quantities are sometimes entered on the claims by the provider. If the MCO does not detect the incorrect quantities, this can cause discrepancies with the number of units shown as dispensed on the claim.



In resolving this type of dispute, the MCO DRAMS contact should review the claims data and determine if the provider billed incorrectly. This will entail looking at the claim; contacting the provider and requesting what the units represent (ML, GRAMS, and EACH). If it is an "each", determine what the "each" represents (capsules, tablets, kits or vials). If the claim was billed incorrectly, the provider must adjust the claim with the correct units.

### 3. Decimals

When the drug strength does not equal a whole number, or the units of measure or package size has a decimal in the units, a decimal point in the units could mean a provider error.

If the MCO does not detect the incorrect quantities, this can cause discrepancies because use of a decimal point may be illogical for many unit types for drug items.

In resolving this type of dispute, the MCO DRAMS contact should review the claims data in question and determine if the provider likely billed incorrectly. It may be necessary to contact the provider if the units are unusual and the MCO DRAMS contact cannot tell whether the provider's units are correct or incorrect.

### 4. Units or Quantities Appear Inconsistent

If the units billed for a particular NDC are inconsistent with the number of prescriptions, the pharmacy reimbursement or lowest dispensable package size, the drug manufacturers will question the amount dispensed, if it appears to be an unexpected amount.

In resolving this type of dispute, the MCO DRAMS contact should review the claims data in question and determine if the provider likely billed incorrectly. It may be necessary to contact the provider if the units are unusual and the MCO DRAMS designate cannot tell whether the provider's units are correct or incorrect.

### 5. Terminated/Invalid NDCs

Terminated NDCs (dispute code N) are those products where the shelf life for the last lot produced has expired. Per CMS guidelines, the affected manufacturer or labeler is required to submit pricing data and pay rebates for 4 quarters past the termination date, but only for claims with a date of service prior to the termination date.

HSD's PBM will contact the manufacturer to obtain the termination date and determine whether the date has been provided to CMS. If advised that a termination date has been sent to CMS and a sufficient amount of time has elapsed since that submission (2 quarters), HSD's PBM will provide the MCO DRAMS contact staff with a list of the providers involved (i.e., those with the most claims for the drug and quarter in question). The MCO DRAMS contact must notify the providers. If the provider has the product on the shelf, they will need to provide the lot number and expiration date and provide the information to staff of HSD's PBM.

Affected claims must be checked to identify all dates of service that fall after the termination date. For those claims, an adjustment must be made. The provider must adjust the claim if the incorrect NDC code was used.

6. State Units Exceed Expected Sales/No Record of Sales in the State

Manufacturers have a threshold on their NDC numbers and if they hit that threshold they will dispute claims based on units exceed expected sales. They also will dispute if they show no record of sales of their product within the state.

In resolving this type of dispute, the MCO DRAMS contact should determine if the provider used the NDC code. Sometimes the provider can show they did order an item from out of state or have other documentation that their billing was correct. The MCO must obtain documentation from the provider of purchase, such as an invoice from their wholesaler with the NDC in question and the amount purchased. This must be forwarded to HSD's PBM so that it may provide the information to the drug manufacturer when requested. Note that the provider must adjust the claim, if the incorrect NDC code was used originally.

7. Inaccurate NDC

A pharmacy or medical provider may submit a claim in which the NDC billed is not the NDC dispensed. In resolving this type of dispute, the MCO should contact the provider and determine if they really used the NDC code reported.

The provider must adjust the claim if the incorrect NDC code was used.

COMMUNICATING WITH HSD's PBM ON DISPUTES AND CORRECTING ERRORS

The MCO is to notify HSD's PBM of claims on which the units were incorrect. HSD's PBM will enter a comment into DRAMS that the units were incorrect and that the MCO is working on adjustments. HSD's PBM will notify the manufacture regarding the status of the dispute.

HSD's PBM cannot change the units on a claim, therefore, it is necessary for the MCO to have the provider adjust the claim. When the encounter data is adjusted, the DRAMS system will back out the incorrect quantity and issue new invoices with the new quantity as a prior quarter adjustment.

If the MCO verifies that some of the disputed quantities are correct, the MCO must notify HSD's PBM. HSD's PBM will enter a comment into DRAMS that the units were correct and state how the quantity was verified such as, a call to the provider. HSD's PBM will notify the manufacturer. The manufacturer may request further documentation such as an invoice from the provider. When further documentation is requested, HSD's PBM will notify the MCO who will be responsible for obtaining the documentation.

**MCO Compliance with the Pharmacy Benefit Manager Regulation Act**

The MCO will ensure that the PBMs are in compliance with the requirements outlined in the Pharmacy Benefit Manager Regulation Act. The MCOs shall ensure that they are monitoring the PBMs' performance on an ongoing basis and that the applicable requirements outlined in 7.14: Major Subcontractors and Subcontractors of the Medicaid Managed Care Agreement are followed.