Pharmacy Coverage Policy Medicare Part D Concurrent DUR Quality Assurance

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare and Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP), and/or Local Coverage Determinations. See the CMS web site at http://www.cms.hhs.gov/. The member's health plan benefits, in effect on the date services are rendered, must be used. Clinical policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in rendering the most appropriate care. Clinical technology is constantly evolving, and Humana reserves the right to review and update this policy periodically.

Description

One of Humana's goals as a Medicare Part D contractor is to ensure that beneficiaries receive safe, high-quality, cost-effective medication therapy. To achieve this goal Humana has entered into a contractual agreement with a claims processor to put certain edits in place to ensure appropriate, safe and effective use of prescription drugs, thereby improving the quality of patient care. These edits improve the overall use of medications through more careful prescribing and dispensing to help prevent patients from taking drugs that may have harmful interactions, prevent patients from receiving higher than recommended doses of a medication, notification of lower cost alternative medications, and provide other safety and efficacy safeguards.

This document details the Drug Utilization Review (DUR) options that can be used by Humana through the claims processor during the processing of prescription drug claims. DUR edits, in conjunction with other benefit edits, are used to meet the following goals:

- Provide guidance to reduce costs
- Prevent over and under utilization
- Provide Concurrent Drug Utilization Review
- Apply Internal Medication Error Identification and Reduction Systems
- Patient education of proper medication use
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Examples of DUR edits are:

- Clinical Use or misuse

- Drug-Drug Interaction
- Age/Gender related contraindications
- Drug-Allergy contraindications
- Drug-Disease contraindications
- Preferred Product
- Duplicate Therapy Monitoring
- Minimum and Maximum Dosage Ranges
- Step Therapy Protocol
- Time Interval Protocols
- Maximum Daily Dose
- Maximum Daily Consumption
- Prior Authorization
- Initial Dose Protocols
- Regulatory limitations

Humana Drug Utilization Review (DUR) is structured as a series of separate programs. They may be used individually or in combination to form the optimum screening environment.

Definition of DUR edits

Drug-Drug Interaction

Drug-Drug Interaction (DDI) screening is used to alert pharmacists of drugs that have been flagged as interactive according to the drug database and user-defined options. A drug interaction occurs when one drug positively or negatively affects another drug.

Possible Drug-Drug Interaction results include inactivation or decreased efficacy of one or both drugs, increased toxicity, efficacy of one or both drugs, or an increase in adverse drug reactions (ADR) from one or both drugs.

The purpose of performing on-line screening for Drug-Drug Interaction is to alert the pharmacist that the patient is taking two drugs with a potentially harmful ADR. This enables the pharmacist to use discretion and intervene, if necessary, to prevent unintentional and/or harmful outcomes for the patient.

Age/Gender Related Contraindications

Age/Gender screening is used to alert pharmacists of drugs that age or gender does not meet manufacturer, Food and Drug Administration, or clinical recommendations for use due to precautions specific to the medication.

The purpose of performing on-line screening for Age/Gender Interaction is to alert the pharmacist that the patient is taking a drug with a potentially harmful ADR as result of their age or gender.
This enables the pharmacist to use discretion and intervene, if necessary, to prevent unintentional and/or harmful outcomes for the patient.

Drug-Allergy Contraindications

Drug-Allergy screening is used to alert pharmacists of drugs that may cause an allergic reaction specific to a given patient. Medications related to those reported by patients as causing some form of allergic reaction are flagged and enable a pharmacist to use discretion and intervene, if necessary, to prevent unintentional and/or harmful outcomes for the patient.

Preferred Product

The preferred product is the most effective treatment according to the health plan's recommendations. Preferred product screening allows the health plan to develop a listing of the drugs with the greatest potential for savings and specify that preferred products be used.

With the preferred product screening option, the pharmacist submitting the prescription receives an on-line notification that the drug being dispensed is not the preferred product. This allows the pharmacist to use discretion and intervene, if appropriate, to prevent unnecessary expense, ineffective treatment, or unpredictable patient outcomes.

Duplicate Therapy Monitoring

Duplicate Therapy Monitoring informs pharmacists that a newly prescribed drug may duplicate the therapeutic effects (Therapeutic Duplication) of another drug already prescribed for an individual patient.

Therapeutic Duplication can occur even when the two drugs are prescribed for different medical conditions. Possible results include additive toxicity and/or an increase in adverse effects.

The purpose of performing on-line screening for Therapeutic Duplication is to alert the pharmacist that the physician is adding a drug that potentially duplicates the therapeutic effects of a drug the patient is currently taking. This enables the pharmacist to use discretion and intervene, if necessary, to prevent unintentional and/or harmful outcomes for the patient.

Minimum and Maximum Dosage Ranges

Minimum and Maximum Dosage Ranges (DR) alert pharmacists when the dose ordered by the physician is either below the minimum or above the maximum recommended dose as determined by the drug database or plan–defined parameters.

A potentially harmful situation arises when a drug is prescribed at a dose significantly above the maximum or below the minimum recommended. A dose below the recommended minimum may be sub-therapeutic (too small to be effective). Inadequate treatment allows the disease or condition to worsen. In addition to being harmful to the patient, treatment of the advanced disease or condition is usually more difficult.

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Doses above the recommended maximum represent potential drug overdose problems. An overdose is either directly toxic to the patient or results in a greater incidence and intensity of side effects. The purpose of performing on-line screening for dosages out of the normal range is to alert the pharmacist that the dose ordered by the physician is either below the minimum or above the maximum recommended dose. This enables the pharmacist to use judgment and intervene, if necessary, to prevent unintentional and/or harmful outcomes for the patient.

Step Therapy

Step Therapy promotes informed drug use and maximizes plan resources by defining how and when a particular drug or drug class should be used. Step Therapy Protocols allow the plan to define a logical sequence of therapeutic alternatives. Step therapy also allows the member to maximize their health care dollars. The plan can control the use of certain drugs or classes of drugs based on previous or concurrent therapy with other drugs following that sequence. Step Therapy requires the use of other therapy (either a drug identified by Generic Code Number (GCN) or any drug within a Specific Therapeutic Class) for a required length of time within a specified time period, before using the requested drug (GCN) or group of drugs.

Time Interval Protocols

Time Interval Protocols allow the plan to specify and limit the number of courses of therapy allowed within a given time period. These algorithms are especially useful for expensive,

non-essential drug therapy that the plan would like to offer, but only on a limited basis. Examples of Time Interval Protocols include allowing a single course of nicotine patches over a member's lifetime, allowing one Exubera® (inhaled insulin) care kit within a calendar or benefit year or limiting H2 antagonist usage at acute doses to eight weeks.

The three types of Time Interval Protocol are as follows:

1. Therapy/Time Interval Protocol. Allows a plan to define the maximum number of days ' therapy allowed for a drug (GCN) or group of drugs in a Specific Therapeutic Class over a specified time frame.
2. Quantity/Time Interval Protocol. Allows a plan to define the maximum quantity allowed for a drug (GCN) or group of drugs in a Specific Therapeutic Class over a specified time frame.
3. Dose/Time Interval Protocol. Allows a plan to define the maximum number of days' therapy allowed for a drug (GCN) or group of drugs in a Specific Therapeutic Class at a particular dose level over a specified time frame.

Maximum Daily Dose

Maximum Daily Dose (MADD) screening allows the health plan to act on prescriptions submitted with directions for use that exceed the maximum recommended dose for the

most common indications. Humana Pharmacy and Therapeutics clinical pharmacy staff identifies MADD values through review of drug information, standard compendia and product labeling.

Maximum Daily Consumption

Maximum Daily Consumption (DACON) allows the health plan to promote efficient drug dosage regimens. Medications selected for the DACON program must:

1. Typically be given as a single daily dose
2. Have multiple strengths available
3. Have a similar price (within 50%) for the next highest dosage strength.

Prior Authorization

To promote the most appropriate utilization, selected high risk or high cost medications require prior authorization by the health plan to be eligible for coverage. Prior Authorization criteria are established by the Pharmacy and Therapeutics Committee with input from providers, manufacturers, peer-reviewed literature, standard compendia and other experts. In order for a member to receive coverage for a medication requiring prior authorization the member's physician must call or fax the plan with appropriate clinical information.

Initial Dose Protocols

Initial Dose Protocols are designed to reduce waste and increase convenience during a trial period for a new or updated dosage regimen. Initial Dose algorithms allow the plan to enforce special restrictions and/or allowances for the initial trial period with a new maintenance medication. Examples of Initial Dose Protocols include restricting new maintenance medications to a ten-day "starter dose."

The DUR system was developed as a tool for pharmacists to screen the medications prescribed for a member. Through the protocols and therapy screenings described in this policy document, the DUR system provides pharmacists with real-time information via a telecommunications network by monitoring all submitted claims. During DUR processing, each claim submitted is compared with other active prescriptions for each individual member and pertinent messages are provided to pharmacists alerting them of potentially harmful situations.

Humana is a Medicare Advantage HMO, PPO and PFFS organization and a stand-alone prescription drug plan with a Medicare contract. Enrollment in any Humana plan depends on contract renewal.
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