

Prior Authorization Protocol

Medicare Part D Tier Exception and Formulary Exception Requests

MCPD

I. FDA Approved Indications:

- All FDA-approved indications not otherwise excluded from Medicare Part D.

II. Health Net Approved Indications and Usage Guidelines:

Tier Exceptions:

- Failure or clinically significant adverse effect to two preferred formulary alternatives
- Chart note documentation may be required
- Eligible tier exceptions:
 - Value (Closed Tier), Classic (Open Tier), and 5 Tier Employer Group formularies
 - From the non-preferred tier (tier 3) to the preferred tier (tier 2)
 - From injectable tier (tier 4) to the preferred tier (tier 2)
 - 4 Tier Employer Group formulary
 - From the injectable tier (tier 3) to the preferred tier (tier 2)

A Formulary Exception request for a non-formulary drug may be approved if:

- Patient has tried and failed or experienced clinically significant adverse effect to:
 - Two or more formulary alternatives that are FDA approved for the requested indication
 - One formulary alternative that is FDA approved for the requested indication if less than two alternatives are available
- AND
- The indication is FDA approved or standard pharmacopeias support efficacy and safety (e.g. DrugDex)
 - Chart note documentation may be required

Exceptions for dose limits, quantity and frequency edits may be approved if:

- Patient has been titrated up from the lower dose with partial improvement without adverse reactions
- AND
- Prescribed dose is FDA approved or standard pharmacopeias support efficacy and safety (e.g. DrugDex)
 - Patient may be required to try formulary alternatives prior to dose escalation if medically appropriate

Formulary exceptions for a brand-name drug request when a generic drug equivalent is available may be approved if:

- Medical justification for brand-name drug instead of generic (e.g., allergy, adverse reaction, etc.) is provided



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III. Coverage is Not Authorized For:

- Specialty Tier (Tier S): (Tier 5 on Value (Closed Tier), Classic (Open Tier), and 5 Tier Employer Group formularies, or Tier 4 on 4 Tier Employer Group formulary) drugs are not eligible for tier exceptions.
- Non-formulary drugs approved through the formulary exceptions process are not eligible for a tier exception.
 - Formulary exceptions approved for Value (Closed Tier), Classic (Open Tier), and 5 Tier Employer Group formularies are approved for a tier 3 co-payment
 - Formulary exception approved for the 4 Tier Employer Group formulary are approved for a tier 2 co-payment.
- Drugs on Tier 2 are not eligible for a tier exception to a Tier 1 co-payment.
- Retro Requests for Tier exceptions will not be covered.

IV. General Information:

- If a Coverage Determination for Benefits request is approved for a medication that requires PA, a Tier Exception request may be approved for the same medication if criteria are met.
- A plan is not required to begin processing an enrollee’s request for a tiering exception until the enrollee’s prescribing physician or other prescriber provides a supporting statement.
- CMS allows Part D sponsors to exempt the Specialty Tier from tier exceptions.
- If a pharmacy waives a copayment at the point of service, this does not constitute a criterion for Health Net to approve exceptions and applies only to that unique episode of dispensing.

V. Therapeutic Alternatives:

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VI. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
Tier exceptions		In effect until the end of the benefit year in which they are approved
Formulary Exception		Length of benefit

VII. Product Availability:

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VIII. References:

1. Medicare Program; Medicare Prescription Drug Benefit; Final Rule. *Federal Register* January 28, 2005.
2. Centers for Medicare & Medicaid Services. CY 2009 Formulary Submission Module & Reports Technical Manual. March 17, 2008.

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3. Medicare Benefit Policy Manual (Chapter 15, Section 50.4.5). Centers for Medicare and Medicaid Website. Available at <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>. Accessed January 14, 2009.
4. Medicare Benefit Policy Manual (Chapter 6, Section 10.6). Centers for Medicare and Medicaid Website Available at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/R2PDB.pdf>. Accessed January 14, 2009.
5. Medicare Benefit Policy Manual (Chapter 6, Section 30.3.5). Centers for Medicare and Medicaid Website Available at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/R2PDB.pdf>. Accessed March 13, 2009.
6. Medicare Benefit Policy Manual (Chapter 6, Section 30.3.3.3). Centers for Medicare and Medicaid Website Available at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/R2PDB.pdf>. Accessed March 13, 2009.
7. Medicare Benefit Policy Manual (Chapter 18, Section 30.2.1).Centers for Medicare and Medicaid Website Available at http://www.cms.gov/manuals/downloads/Pub100_18.pdf. Accessed September 16 2010.
8. Centers for Medicare & Medicaid Services. 2010 Call Letter. Available at <https://www.cms.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf>. Accessed April 8, 2011.

The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.