Prior Authorization Protocol

2016 Medicare Part D Tier Exception and Formulary Exception Requests

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I. **FDA Approved Indications**:

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

II. **Health Net Approved Indications and Usage Guidelines:**

Drugs without a New Drug Application (NDA), Abbreviated New Drug Application (ANDA) or Biologics License Application (BLA), also known as "No NDA/ANDA or BLA drugs"

- Are not eligible for formulary exception.

Tier Exceptions:

- Failure or clinically significant adverse effect to two formulary alternatives (or one formulary alternative if only one is available) that are in a lower tier than the requested drug and, are FDA approved or standard pharmacopeias (e.g. DrugDex) support efficacy and safety for the requested indication. Note: Tier 6 "Select Care Tier" drugs qualify as lower tier alternatives.

AND

- The indication is FDA approved or standard pharmacopeias (e.g. DrugDex) support efficacy and safety

AND

- Chart note documentation may be required

AND

- Eligible tier exceptions:
    - Employer Group formulary
        - From the non-preferred brand drug tier (Tier 3) to the preferred brand drug tier (Tier 2) if there is at least one preferred (Tier 2) formulary alternative
        - For a brand drug in the injectable drug tier (Tier 4) to the preferred brand drug tier (Tier 2) if there is at least one preferred (Tier 2) formulary alternative
        - For a generic drug in the injectable drug tier (Tier 4) to the preferred generic drug tier (Tier 1) if there is at least one preferred (Tier 1) formulary alternative
    - Value formulary
        - From the generic drug tier (Tier 2) to the preferred generic drug tier (Tier 1) if there is at least one preferred (Tier 1) formulary alternative
        - For a generic drug in the preferred brand drug tier (Tier 3) to the preferred generic drug tier (Tier 1) if there is at least one preferred (Tier 1) formulary alternative

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- o For a generic drug in the non-preferred brand drug tier (Tier 4) to the preferred generic drug tier (Tier1) if there is at least one preferred (Tier 1) formulary alternative
- o For a brand drug in the non-preferred brand drug tier (Tier 4) to the preferred brand drug tier (Tier 3) if there is at least one preferred (Tier 3) formulary alternative

Formulary Exceptions for a non-formulary drug (not applicable to formulary exceptions for a brand name drug when a generic drug equivalent is available and not applicable to No NDA/ANDA or BLA drugs):

- Failure or clinically significant adverse effect to:

    - Two or more formulary alternatives that are FDA approved or standard pharmacopeias (e.g. DrugDex) support efficacy and safety for the requested indication

    - One formulary alternative that is FDA approved or standard pharmacopeias (e.g. DrugDex) support efficacy and safety for the requested indication if only one is available

    OR

    - Prescriber has indicated the alternative(s) listed on the formulary or step therapy requirement(s) is likely to cause an adverse reaction or harm

    AND

- The indication is FDA approved or standard pharmacopeias (e.g. DrugDex) support efficacy and safety

    AND

- Chart note documentation may be required

Formulary Exceptions for a drug with electronic step therapy (EST) requirements:

- The indication is FDA approved or standard pharmacopeias (e.g. DrugDex) support efficacy and safety

AND

- Failure or clinically significant adverse effect to the formulary alternative(s) listed in the electronic step therapy

    OR

- Prescriber has indicated the alternative(s) listed on the formulary or step therapy requirement(s) is likely to cause an adverse reaction or harm

    OR

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- Failure or clinically significant adverse effect to two or more formulary alternatives that are FDA approved or standard pharmacopeias (e.g. DrugDex) support efficacy and safety for the requested indication

Formulary exceptions for dose limits, quantity and frequency edits:

- Patient has been titrated up from the lower dose with partial improvement without adverse reactions

  AND

- Prescribed dose is FDA approved or standard pharmacopeias (e.g. DrugDex) support efficacy and safety

  AND

- The dose requested cannot be achieved by using other strengths of the medication that are within the formulary quantity limits

  AND

- Patient may be required to try formulary alternatives prior to dose escalation if medically appropriate

Formulary exceptions for a brand-name drug when a generic drug equivalent is available:

- Failure or clinically significant adverse effects to the generic equivalent

  AND

- The indication is FDA approved or standard pharmacopeias (e.g. DrugDex) support efficacy and safety

III. **Coverage is Not Authorized For:**

- Drugs on Tier 5 (specialty tier) are not eligible for tier exceptions.
- Drugs on the Select Care (SC) tier are not eligible for tier exceptions.
- Drugs are not eligible for tier exceptions to the Select Care (SC) tier.
- Drugs with no available preferred tier formulary alternatives are not eligible for tier exceptions.
- Drugs covered under the transition fill program are not eligible for tier exceptions.
- Preferred brand drugs (Tier 3 on Value or Tier 2 on Employer Group formularies) are not eligible for tier exceptions.
- Non-formulary drugs approved through the formulary exceptions process are not eligible for tier exceptions.
  - Formulary exceptions approved for the Value formulary are approved for a Tier 4 co-payment.

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- o Formulary exceptions approved for the Employer Group formulary are approved for a Tier 3 co-payment.

IV. **General Information:**

- Covered Part D compounded drugs will process with the tier copay associated with the highest cost paid ingredient. If the highest tier ingredient in the compound is eligible for a tier exception, the compound may be eligible for a tier exception if criteria are met.
- No NDA/ANDA or BLA drugs are identifiable in Formulary Viewer with messaging next to the drug and may be based on GPI or NDC.
- 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.
- CMS allows Part D sponsors to exempt the Specialty Tier from tier exceptions.
- Specific drug formulary status may vary upon each calendar year. Retroactive tier requests will be back dated up to the member's initial coverage date in the current benefit year.
- 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:**

This section intentionally left blank

VI. **Recommended Dosing Regimen and Authorization Limit:**

Drug	Dosing Regimen	Authorization Limit
Tier exceptions	This field intentionally left blank.	In effect until the end of the calendar year in which they are approved Retroactive requests: Back dated up to the member's initial coverage date in the current benefit year
Formulary Exception	This field intentionally left blank.	Length of benefit

VII. **Product Availability:**

This section intentionally left blank

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.
9. Medicare Prescription Drug Benefit Manual (Chapter 18, Section 30.2).Centers for Medicare and Medicaid Website Available at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html. Accessed November 16, 2014.

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.