Clinical Policy: Formulary Exceptions

Reference Number: CP.CPA.190
Effective Date: 11.16.16
Last Review Date: 11.23
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

This policy applies to requests for formulary exceptions and/or when specific prior authorization criteria do not exist.

FDA Approved Indication(s)

Varies by drug product.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that formulary exceptions are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Exceptions for Non-Formulary or Tier 3 Drugs (must meet all)**:**

Not applicable to formulary exceptions for a brand name drug when a generic drug equivalent is available (see Section ID below); Tier 3 exceptions apply to plans where prior authorization is required for all Tier 3 drugs

1. Prescribed indication is FDA-approved;*
   ** Requests for off-label use should also be reviewed against CP.CPA.09 – Off-Label Drug Use*
2. For mental health and substance use disorder medications, use is supported by non-profit professional associations guidelines (*see Appendix E*);
3. Request is not for a benefit excluded use* (e.g., cosmetic);
   ** Per California state regulations, **medical** benefit requests for Sculptra® and Radiesse® for members with HIV is not considered an excluded benefit*
4. Failure of at least two formulary alternatives within the same therapeutic class that are FDA-approved for the same indication and/or drugs that are considered the standard of care for the indication, when such alternatives exist, at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment, unless clinically significant adverse effects are experienced or all are contraindicated;
5. Trial and failure of formulary agents is supported by one of the following (a, b, c, or d):
   a. Presence of claims in pharmacy claims history supporting failure of formulary alternatives as described in criteria 2 above;

b. Documented contraindication(s) or clinically significant adverse effects to **all** formulary agents within the same therapeutic class or formulary drugs that are recognized as standards of care for the treatment of member's diagnosis;
c. Drug sample logs which include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;
d. Documentation in provider chart notes which include all of the following: medication name, dose/strength, and start/end dates of therapy;

6. For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths** (e.g., contraindications to the excipients of all alternative products);
   **Use of a copay card or discount card does not constitute medical necessity*
   *** Compounding kits are non-formulary, member must try formulary options if appropriate and standard compounding processes.*
7. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Injectables - 6 months or to the member's renewal date, whichever is longer
All other requests - 12 months or duration of request, whichever is less

B. Exceptions to Quantity Limit (must meet all)**:**

1. One of the following (a, b, c, d, or e):
   a. Requested dose is supported by practice guidelines or peer-reviewed literature (e.g., phase 3 study or equivalent published in a reputable peer reviewed medical journal or text) for the relevant off-label use and/or regimen (*prescriber must submit supporting evidence*), or for mental health and substance use disorder medications use is supported by non-profit professional associations guidelines (*see Appendix E*), and member has been titrated up from the lower dose with partial improvement without adverse reactions (dose optimization is required, refer to the dose-optimization criteria in Section IC below);
   b. Diagnosis of a rare condition/disease* for which FDA dosing guidelines indicate a higher quantity (dose or frequency) than the currently set quantity limit (QL), and member has been titrated up from the lower dose with partial improvement without adverse reactions (dose optimization is required; refer to the dose-optimization criteria in Section IC below);
      **Example: Proton pump inhibitors, which are commonly used for gastroesophageal reflux disease, have a QL of one dose per day; however, when there is a rare diagnosis such as Zollinger-Ellison syndrome, an override for two doses per day is allowed*
   c. Request is for a condition eligible for continuity of care (e.g., seizures, heart failure, human immunodeficiency virus infection, and psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology), and therapy will be titrated to be within the currently set QL (refer to the dose-optimization criteria in Section IC below);

d. Request is for pain management in cancer, sickle cell anemia, palliative care, or end of life care;
e. Request is for pain management and both of the following (i and ii):
   i. Member has a signed treatment plan specific to his/her care with a single qualified prescriber;
   ii. Prescriber has provided his/her plan of action (which may include historical titration schedule to the current dose and/or titration schedule to decrease the dose to be within the currently set QL [refer to the dose-optimization criteria in Section IC below]);

2. Failure of preferred alternatives prior to dose escalation may be required if medically appropriate.

Approval duration:
Pain management in cancer, sickle cell anemia, palliative care, end of life care – 12 months or duration of request, whichever is less
All other indications – 3 months

C. Exceptions to Dose Optimization (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Dose titration: Multiple lower strength units are requested for the purpose of dose titration;
   b. Other clinical reasons: Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen;
2. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA-recommended regimen and maximum daily dose;
   b. For QL exceptions, refer to Section IB above.

Approval duration:
Dose titration – 3 months
Injectables - 6 months or to the member's renewal date, whichever is longer
All other requests - 12 months or duration of request, whichever is less

D. Exceptions for Brand Name Drug When a Generic Equivalent is Available (must meet all)**:**

1. Prescribed indication is FDA-approved;*
   ** Requests for off-label use should also be reviewed against CP.CPA.09 – Off-Label Drug Use*
2. For mental health and substance use disorder medications, use is supported by non-profit professional associations guidelines (*see Appendix E*);
3. Request is not for a benefit excluded use* (e.g., cosmetic);
   ** Per California state regulations, **medical** benefit requests for Sculptra® and Radiesse® for members with HIV is not considered an excluded benefit*
4. Failure of an adequate trial of or clinically significant adverse effects to two generics* (each from a different manufacturer) or the preferred biosimilar(s) of the requested brand name drug, unless member has contraindications to the excipients in all generics/biosimilars;
   **If a second generic of the requested brand name drug is not available, member must try a formulary alternative that is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex) for the requested indication, provided that such agent exists*

5. Provider submits clinical rationale* supporting why the brand name drug will be more effective than the generic or will not produce the same adverse effects as the generic;
   **Use of a copay card or discount card does not constitute medical necessity*
6. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Injectables - 6 months or to the member's renewal date, whichever is longer
All other requests - 12 months or duration of request, whichever is less

E. Exceptions for Combination Products and Alternative Dosage Forms or Strengths of Existing Drugs (must meet all)**:**

1. Prescribed indication is FDA-approved;*
   ** Requests for off-label use should also be reviewed against CP.CPA.09 – Off-Label Drug Use*
2. For mental health and substance use disorder medications, use is supported by non-profit professional associations guidelines (*see Appendix E*);
3. Request is not for a benefit excluded use* (e.g., cosmetic);
   ** Per California state regulations, **medical** benefit requests for Sculptra® and Radiesse® for members with HIV is not considered an excluded benefit*
4. Medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths** (e.g., contraindications to the excipients of all alternative products);
   **Use of a copay card or discount card does not constitute medical necessity*
   *** Compounding kits are non-formulary, member must try formulary options if appropriate and standard compounding processes.*
5. Failure of at least two formulary alternatives within the same therapeutic class that are FDA-approved for the same indication and/or drugs that are considered the standard of care for the indication, when such alternatives exist, at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment, unless clinically significant adverse effects are experienced or all are contraindicated;
6. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Injectables - 6 months or to the member's renewal date, whichever is longer
All other requests - 12 months or duration of request, whichever is less

F. Exceptions for Drugs Requiring Prior Authorization without Custom Coverage Criteria or Pending Clinical Policy Updates as a Result of Recent Label Changes (must meet all)**:**

1. Request is for a drug on the formulary*;

**All requests for non-formulary drugs, should be reviewed against Section IA Exceptions for Non-Formulary or Tier 3 Drugs above*

2. Request is not for a benefit excluded use* (e.g., cosmetic);
   ** Per California state regulations, **medical** benefit requests for Sculptra® and Radiesse® for members with HIV is not considered an excluded benefit*
3. One of the following (a or b):
   a. Requested drug does not have a drug-specific clinical policy or custom coverage criteria;
   b. Requested drug has a drug-specific clinical policy that is pending clinical policy updates as a result of recent (within the last 6 months) label changes (e.g., newly approved indications, age expansions, new dosing regimens);
4. Diagnosis of one of the following (a or b):
   a. A condition for which the product is FDA-indicated and -approved;
   b. A condition supported by the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B;
   c. For mental health and substance use disorder medications, use is supported by non-profit professional associations guidelines (*see Appendix E*);
5. Failure of at least two formulary alternatives within the same therapeutic class that are FDA-approved for the same indication and/or drugs that are considered the standard of care for the indication, when such alternatives exist, at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment, unless clinically significant adverse effects are experienced or all are contraindicated;
6. Member has no contraindications to the prescribed agent per the prescribing information;
7. If applicable, prescriber has taken necessary measures to minimize any risk associated with a boxed warning in the product information label;
8. For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths** (e.g., contraindications to the excipients of all alternative products);
   **Use of a copay card or discount card does not constitute medical necessity*
   *** Compounding kits are non-formulary, member must try formulary options if appropriate and standard compounding processes.*
9. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Injectables - 6 months or to the member's renewal date, whichever is longer
All other requests - 12 months or duration of request, whichever is less

II. Continued Therapy

A. All Exceptions in Section I (must meet all)**:**

1. One of the following (a, b, or c):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
c. Health plan continuity of care programs apply to the requested drug and indication (e.g., seizures, heart failure, human immunodeficiency virus infection, and psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology) with documentation that supports that member has received this medication for at least 30 days;

2. Member is responding positively to therapy;
3. For QL exception requests for dose titrations, one of the following (a or b):
   a. Documentation supports the continued need for dose titration or medical justification supports inability to use the higher strength units to achieve the desired dose/regimen;
   b. Medical justification supports continued need for quantities above the QL;
4. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
QL exceptions for continued dose titrations – 3 months
Injectables - 6 months or to the member's renewal date, whichever is longer
All other requests - 12 months or duration of request, whichever is less

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Varies by drug product

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information

- A generic drug is identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Generic substitution is mandatory when A-rated generic equivalents are available; however, brand name drugs may be approved in certain circumstances where there are adverse reactions to or therapeutic failure of generic drugs. Examples of failure of a generic drug include:

- Suboptimal drug plasma levels while taking the generic drug as compared to drug plasma levels while taking the brand name drug;
- Increase or worsening in symptoms (e.g., increase in seizure activity) when switched to a generic drug that is not attributed to progression of the disease state, increase in member age or weight, or member non-compliance.

- Dose optimization is the consolidation of multiple units of lower strength to the fewest units required to achieve the desired daily dose/regimen based on commercially available dosage strengths. Requests for multiple units of a lower strength will be denied when the plan approved QL for such medication is exceeded and higher strength units are commercially available to achieve the desired daily dose/regimen.

Request Example	Prescribed Regimen	Approvable Regimen
Request for Seroquel XR 800 mg/day	Seroquel XR 200 mg tablets, 4 tablets/day	Seroquel XR 400 mg tablets, 2 tablets/day
Request for aripiprazole 30 mg/day	Aripiprazole 15 mg tablets, 2 tablets/day	Aripiprazole 30 mg tablet, 1 tablet/day

Appendix E: Non-Profit Association Guidelines for Mental Health and Substance Use Disorder

The following are non-profit professional associations guidelines and these criteria should be referenced to make utilization review decisions. When non-profit associations guidelines are not available or are not specific or current enough to address treatment, criteria will follow generally accepted standards of mental health and substance use disorder care and any advancements in technology.

- American Academy of Child and Adolescent Psychiatry.
- American Academy of Family Physicians.
- American Academy of Neurology.
- American Academy of Pediatrics.
- American Academy of Sleep Medicine.
- American Association for Community Psychiatry.
- American College of Physicians.
- American Medical Association.
- American Psychiatric Association.
- American Psychological Association.
- American Society of Addiction Medicine.
- Canadian Network for Mood and Anxiety Treatments.
- Counsel of Autism Providers.
- Substance Abuse and Mental Health Services Administration (SAMHSA).
- World Professional Association for Transgender Health (WPATH).

V. Dosage and Administration

Varies by drug product

VI. Product Availability

Varies by drug product

VII. References

Not applicable

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2019 annual review: exceptions for non-formulary or tier 3 drugs: added that trial and formulary agents must be supported by claims, documentation of adverse effects, sample logs, or chart notes; references reviewed and updated.	08.27.19	11.19
Replaced the terms "PDL" to "formulary" agents.	05.11.20	
4Q 2020 annual review: for I.B Exceptions to Quantity Limit, removed cross reference to the off-label use policy per PA Ops request; for I.A Exceptions for Non-Formulary or Tier 3 Drugs and I.F Exceptions for Drugs Requiring Prior Authorization without Custom Coverage Criteria, added bypass of required formulary alternative trials if clinically significant adverse effects are experienced or all are contraindicated; for I.D Exceptions for Brand Name Drug When a Generic Equivalent is Available, added redirection to preferred biosimilar products; for I.F, added requirement that member does not have labeled contraindications and that the prescriber has mitigated boxed warning risks; for drugs requiring prior authorization without custom coverage criteria and non-formulary or tier 3 exceptions added criteria for combinations products and alternative dosage forms or strengths of existing drugs; clarified claims history for non-formulary/tier 3 exceptions must support requirements for failure of formulary alternatives; added bypass of required preferred agent trials if clinically significant adverse effects are experienced or all are contraindicated; references reviewed and updated.	07.13.20	11.20
4Q 2021 annual review: no significant changes; for Exceptions for Drugs Requiring Prior Authorization without Custom Coverage Criteria, added requirement for an FDA-approved or compendium-supported diagnosis to align with the previously Corporate P&T-approved approach; add clarification and reference to off-label use policy.	07.22.21	11.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	09.27.21	02.22
4Q 2022 annual review: clarified and expanded criteria to apply to recent label changes pending clinical policy updates; references reviewed and updated. Template changes applied to continued therapy section.	08.02.22	11.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added to Section I.F requirement that request is not for a benefit excluded use (e.g., cosmetic) with clarification that per California state regulations, medical benefit requests for Sculptra and Radiesse for members with HIV is not considered an excluded benefit.	04.18.23	
4Q 2023 annual review: added injectable specific approval duration of "6 months or to the member's renewal date, whichever is longer" to all criteria sets other than exceptions to quantity limits; added requirement from Section I.F that request is not for a benefit excluded use to all criteria sets other than exceptions to quantity limits and dose optimization.	06.23.23	11.23
Added clarification that "Compounding kits are non-formulary, member must try formulary options if appropriate and standard compounding processes"	06.25.24	
Due to updates from SB855, added information regarding non-profit professional associations guidelines that should be referenced to make utilization review decisions. Added Appendix E that states "When non-profit guidelines are not available or are not specific or current enough to address treatment, criteria will follow generally accepted standards of mental health and substance use disorder care and any advancements in technology."	07.17.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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