Non-Preferred Drug with Continuation of Therapy Prior Authorization Program Summary

This program applies to Medicaid.

Requests for an oral liquid form of a drug must be approved if BOTH of the following apply:

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY REVIEW CYCLE

Effective Date	Date of Origin
06-01-2024	07-01-2019

FDA APPROVED INDICATIONS AND DOSAGE

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Application	These criteria apply to non-preferred drugs listed in the Minnesota Medicaid Preferred Drug List (PDL).[1] These criteria apply only to FDA approved legend drugs which are covered under the member's current benefit plan. Medications which are investigational or otherwise not a covered benefit should be forwarded for review under the appropriate process.

REFERENCES

Number	Reference
1	Uniform Preferred Drug List (PDF). Minnesota Department of Human Services. https://mn.gov/dhs/partners-and-providers/policies-procedures/minnesota-health-care-programs/provider/types/
2	Non-Preferred Drug Prior Authorization Criteria. Minnesota Department of Human Services. Last updated: October 2021. https://mn.gov/dhs/partners-and-providers/policies-procedures/minnesota-health-care-programs/provider/types/
3	Continuation of Therapy Prior Authorization Criteria. Minnesota Department of Human Services. Last updated: February 2019. https://mn.gov/dhs/partners-and-providers/policies-procedures/minnesota-health-care-programs/provider/types/

CLIENT SUMMARY – PRIOR AUTHORIZATION

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Non-Preferred Drug Prior Authorization Criteria[2] December 2023 **Approval Criteria:** A request for coverage of a non-preferred drug may be approved if the following criteria are met: 1. The drug is not excluded from coverage (for example, drugs for erectile dysfunction) **AND** 2. The drug is prescribed for a medically accepted indication as defined in Section 1927 of the Social Security Act **AND** 3. The request is for an oral liquid form of a drug and the patient utilizes an enteral tube for feeding or medication administration **OR** 4. The member has been taking the requested nonpreferred drug to treat a mental illness or emotional disturbance as defined by Minnesota Statute, 62Q.527 for at least 90 days **OR** 5. The preferred drugs are experiencing documented drug shortages or recalls from a wholesaler, manufacturer, the ASHP (American Hospital of Health-System Pharmacist) Drug Shortage web page or The US Food and Drug Administration **OR** 6. The requested drug is being prescribed within recommended dosing guidelines **AND** 7. The member has had a trial of at least two preferred chemically unique drugs within the same drug class on the Preferred Drug List, or a trial of at least one preferred drug within the same drug class if there are not two chemically unique preferred drugs within the same drug class. The use of free goods or pharmaceutical samples will not be considered as meeting any step of the nonpreferred drug prior authorization criteria **AND (at least one of the following)** A. The prescriber must provide documentation (for example, pharmacy dispensing record, medication orders in members' health record, and so forth) at the time of request showing that: 1. the member adhered to the previous therapies during the trial(s) **AND** 2. the trial period was sufficient to allow for a positive treatment outcome, or that the drug was discontinued due to an adverse event **OR** B. The member is currently taking the requested nonpreferred drug and is experiencing a positive therapeutic outcome **AND** the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member, or that the preferred drug would be ineffective **OR** C. The preferred drug is contraindicated pursuant to the pharmaceutical manufacturer's prescribing information or, due to a documented adverse event or medical condition, is likely to result in the following: 1. cause an adverse reaction **OR** 2. decrease the ability of the member to achieve or maintain reasonable functional ability in performing daily activities **OR** 3. cause physical or mental harm to the member **Duration of Approval** • Requests due to drug shortages: o The Department of Human Services (DHS) may approve the request up to 3 months or up to the estimated known and verifiable resolution date, if the documented drug shortages are from the wholesaler (for example, wholesaler invoice, screenshot of wholesaler electronic ordering system, and so forth). o DHS may approve the request up to 6 months or up to the estimated known and verifiable resolution date, if the documented drug shortages are from the manufacturer (for example, manufacturer press release, screenshot of manufacturer web page, and so forth). o DHS may approve the request up to 12 months or up to the estimated known and verifiable resolution date, if the documented drug shortages are from the ASHP Drug Shortages web page or US Food and Drug Administration • DHS may approve requests due to other reasons up to 12 months

Module	Clinical Criteria for Approval
	Quantity Limits • Quantity limits pursuant to the FDA-approved label will apply **Note** • If applicable, the nonpreferred drug prior authorization criteria does not replace the requirement for a clinical prior authorization for a specific drug • The inability or unwillingness of the enrolled pharmacy to order or stock the preferred drug will not be considered as a basis for requests due to drug shortages **Definition** • Free goods or pharmaceutical samples: medication samples, medications obtained from any patient assistance programs or any discount programs, medications obtained through free trial programs, manufacturer vouchers, coupons or debit cards while the member is on Medical Assistance. **<u>Continuation of Therapy Prior Authorization Criteria</u>[3]** February 2019 **Definitions** • **Biosimilar Substitution:** Dispensing a biosimilar product rather than the reference biologic product. • **Cash Pay:** Allowing a member to pay for the entire cost of a non-covered prescription, after a member, in consultation with the prescriber and the pharmacist, has decided that covered alternatives are not options. A member may pay for the entire cost of a non-covered controlled substance prescription, including gabapentin, only when the member meets all conditions specified in the Advanced Recipient Notice of Non-Covered Prescription Form (DHS-3641-ENG) • **Continuation of Therapy:** Allowing a member who has been stabilized on a medication that requires prior authorization, but was previously covered by another payer (i.e., commercial insurance, MCO Medicaid plans), to continue the therapy without the prescriber having to satisfy the fee-for-service prior authorization criteria. • **Free goods/pharmaceutical samples:** Medication samples, medications obtained from any patient assistance programs, medications obtained through free trial programs, manufacturer vouchers, coupons or debit cards. • **Generic Substitution:** Dispensing a generically equivalent drug rather than the brand name drug. **Approval criteria** Continuation of Therapy override may be approved for nonpreferred or restricted drugs if the following conditions are met: 1. The requested nonpreferred or restricted drugs are not excluded from coverage (e.g., drugs for weight loss, drugs for erectile dysfunction) **AND** 2. The requested nonpreferred or restricted drugs are prescribed for a medically accepted indication as defined in Sec. 1927 of the Social Security Act **AND** 3. The member has been treated with a nonpreferred or restricted drug at a consistent dosage for at least 90 days and the prescriber indicates (orally or in writing) that the prescribed medication will best treat the member's condition **AND**

Module	Clinical Criteria for Approval
	4. The pharmacy or prescriber must provide an attestation that the medication was covered by another payer and not obtained via cash pay, drug manufacturer-issued debit cards, or via free goods/pharmaceutical samples. **Duration of Approval** 1. Continuation of Therapy override may be approved for up to 90 days. After 90 days, the prescriber must obtain prior authorization for the nonpreferred or restricted drug or transition the member to an alternative therapy. Multiple Continuation of Therapy overrides will not be approved for the same drug **OR** 2. If the member has an existing approved prior authorization (PA) for the nonpreferred or restricted drugs, then the member's previously approved PA will be approved until the PA expires **OR** 3. If the member has received a prescribed drug to treat a mental illness or emotional disturbance as defined by Minnesota Statute 62Q.527, the member may continue to receive coverage for such prescribed drugs for up to one year. **Continuation of Therapy criteria overrides are not available to bypass generic or biosimilar substitution (if applicable).** **Free goods/Pharmaceutical Samples Policy** The use of free goods or pharmaceutical samples will not be considered as meeting the 90-day treatment requirement for Continuation of Therapy overrides. A member, after meeting all conditions for cash pay, must pay for the entire cost of the non-covered prescription.

