Oscar Clinical Guideline: Brand Medically Necessary Drugs (PG186, Ver. 3)

Brand Medically Necessary Drugs

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

This clinical prior authorization policy outlines the coverage criteria for Brand drugs that have been defined as Brand Medically Necessary (BMN) drugs by the Plan. It includes criteria for initial authorization, reauthorization, coverage for unavailable generics, and certain exclusions from coverage. The policy aims to ensure that coverage is provided based on medical necessity and appropriate documentation.

Table 1: Brand Medically Necessary Drugs Subject to Clinical Prior Authorization

Medication	Brand[α]	Generic
Lisdexamfetamine Dimesylate	Vyvanse Chewable tablet, capsule	❖ Lisdexamfetamine Dimesylate Chewable tablet

Medication	Brand[ɴ]	Generic
		❖ Lisdexamfetamine Dimesylate Oral capsule
sodium phenylbutyrate	Buphenyl Tablet, Powder for Solution	❖ Sodium Phenylbutyrate Oral tablet ❖ Sodium Phenylbutyrate Powder for oral solution

[ɴ]Subject to Brand Medically Necessary Drugs Clinical Prior Authorization Policy

Definitions

"**Brand Medically Necessary (BMN) Drugs**" refers to specific brand-name drugs (see **Table 1**, above) that have a generic equivalent and have been identified by the health plan as brand products with criteria for establishing medical necessity over the generic. These drugs are subject to coverage criteria outlined in this policy, including requirements to demonstrate unsatisfactory therapeutic response or intolerable adverse event (e.g., clinically significant adverse effects) when using generic versions of the drug from different manufacturers.

"**Compendia**" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Elsevier Clinical Pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"**Clinically significant adverse effects**" refer to harmful or dangerous reactions that may be experienced when using a drug. These are side effects that pose a serious health risk requiring discontinuation of the drug (e.g., liver damage, severe allergic reactions, cardiac arrhythmias).

"**Contraindication**" refers to a pre-existing condition or factor that precludes use of a drug due to risk of harm.

"**Documentation**" refers to written information, including but not limited to:

1. Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses;

2. Prescription claims records, and/or prescription receipts to support prior trials of alternatives.

"**Experimental or Investigational**" are procedures, drugs, or devices that haven't been proven effective or which haven't been approved by the appropriate regulatory bodies.

"**FDA**" refers to the Federal Food and Drug Administration.

"**Intolerance**" refers to the inability to tolerate or endure something, often due to experiencing subjectively difficult or harmful side effects, reactions, or hypersensitivities when using a medication or treatment that negatively impacts quality of life, ability to adhere, or overall health. Documentation is expected to detail the specific intolerable effects and their impact on treatment.

"**Off-Label Uses**" is use of a medication for clinical indications other than those approved by the Food and Drug Administration (FDA).

"**Prior Authorization (PA)**" is a requirement that the provider obtain advance approval from the Plan that coverage criteria are met before the drug will be covered.

"**Step Therapy**" is a requirement to try another drug (usually a generic or preferred option) first before moving to a higher cost medication.

"**Therapeutic Failure**" refers to an unsatisfactory clinical response to a medication, indicated by lack of effectiveness, worsening disease, recurrence of symptoms, intolerable side effects, or inability to maintain adequate blood levels/responses.

Medical Necessity Criteria for Initial Authorization

For Brand name products that the Plan has defined as a **Brand Medically Necessary (BMN) Drug** (see Table 1, above), coverage will be authorized when **ALL** of the following criteria are met:

1. The member meets the Plan's established coverage and prior authorization (PA) criteria for the generic drug, if applicable. This may include:
    a. Step therapy requirements; ***and/or***
    b. Clinical PA criteria; ***and/or***
    c. Drug class-specific PA requirements; ***AND***
2. There is clinical documentation demonstrating **EITHER**:

a. The member experienced unsatisfactory therapeutic response or intolerable adverse events when trying the generic formulation of this drug from at least two different manufacturers (if available); ***or***
b. The member has a contraindication to generic products from **ALL** available manufacturers that would **NOT** exist or be reasonably expected to occur with the requested Brand Product; ***AND***

3. The prescriber has submitted detailed documentation of the member's relevant medication treatment history, including:
    a. Name, manufacturer/NDC, dose, frequency, and duration of the generic drug(s) tried; ***and***
    b. Approximate dates of prior generic drug trial(s); ***and***
    c. Reported therapeutic response and/or adverse effects for each generic drug trial; ***AND***

    Documentation may come from the pharmacy or the prescriber.
    d. As applicable:
        i. The prescriber indicates how the BMN drug will prevent recurrence of therapeutic failure or adverse effects experienced with the generic.
        ii. Documented contraindication or clinical reason to avoid generic products from **ALL** available manufacturers.

If the above prior authorization criteria are met, the requested Brand name product will be authorized for up to 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12-months will be granted if the member has recent (within the last 6 months) clinical chart documentation demonstrating **ALL** of the following criteria:

1. Documented maintenance, stability or improvement in the condition/disease that was the indication for the original approval, validated by clinical documentation such as:
    a. Disease activity scores; ***and/or***
    b. Symptom evaluation; ***and/or***
    c. Imaging results; ***and/or***
    d. Laboratory values; ***AND***
2. Provider attestation that the drug continues to be safe and effective for the member; ***AND***
3. The member continues to receive monitoring and follow-up assessments at regular intervals.

Coverage Criteria for Unavailable Generics (i.e., Generic Drugs Not Available in the Marketplace)

Brand drugs may be approved on a one-time basis if the following criteria are met:

1. the generic equivalent drug is not available in the marketplace due to ANY of the following:
    a. temporary manufacturing discontinuation; ***or***
    b. manufacturer drug shortage, or backorder; ***and***
2. There is documentation from the FDA drug shortages webpage or the ASHP drug shortages webpage confirming a nationwide shortage; ***AND***
3. The member's pharmacy and regular wholesaler confirm being out of stock of the needed generic formulation.

Additional Notes:

1. *Brand drugs approved due to generic unavailability may be subject to the health plan's applicable tier copayment (e.g., brand, non-preferred, specialty).*
2. *Reauthorization of brand coverage will not be approved beyond the documented timeframe of the temporary generic market shortage.*
3. *Isolated events of the member's preferred pharmacy being out of stock or the pharmacy's regular wholesaler being out of stock of the generic is not a sufficient reason for approval.*
4. *Upon expiration of a shortage exception approval, a request to continue brand coverage would require a reassessment of current medical necessity by standard reauthorization criteria:*
    a. *Brand approvals granted due to a temporary generic shortage are exception-based and do not constitute an approval of medical necessity of the brand product.*
    b. *Shortage exception approvals provide coverage only for the documented duration of the shortage and do not equate to reauthorization approvals based on medical necessity criteria.*

Experimental or Investigational / Not Medically Necessary

Use of the Brand drug for any indication deemed experimental, investigational or unproven by Plan is not covered. Non-covered indications include, but are not limited to (not all-inclusive):

1. Off-label uses considered not medically necessary, including those that are:
    a. Outside of FDA-approved or compendia-supported age limits.
    b. At dosing deemed unsafe (dose, frequency, duration, route not appropriate).
    c. Contraindicated based on comorbidities or drug interactions.
2. Uses not aligned with generally accepted medical practice, or accepted in evidence-based guidelines from professional societies.
3. Uses that do not meet requirements for medical need based on indication, including:

a. Treatment is not essential for management of a member's medical condition.
b. Use is primarily for convenience/preference of member, family, or provider.

Additionally:

4. Member/prescriber preference for the Brand drug is not sufficient criteria to establish medical necessity over the generic equivalent.
5. Use of copay coupon programs does not justify approving the Brand over generic formulations.

References

1. Center for Drug Evaluation and Research. "Drug Shortages." U.S. Food and Drug Administration, 2019, www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.
2. "Drug Shortages - ASHP." American Society of Health-System Pharmacist, https://www.ashp.org/drug-shortages.

Clinical Guideline Revision / History Information

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