Clinical Policy: Brand Name Override

Reference Number: HNCA.CP.PMN.22
Effective Date: 11.01.18
Last Review Date: 07.11.23
Line of Business: California Commercial Members

Revision Log

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

Description

Health Net commercial plans offer three different plan options to obtain a brand name drug when a generic equivalent is available.

Definitions

The MAC A option allows a DAW 1 and DAW 2 to process through the pharmacy claims system charging a copayment (the generic copayment for DMHC governed plans and the Brand or Non-preferred copayment for CDI governed plans) **plus** the difference between the Brand and the generic (MAC'd) price.

The MAC B option allows a DAW 1 to process through the pharmacy claims system charging the Brand, the Non-preferred copay or Specialty copay (if the drug is a Specialty Drug) and DAW 2 to process through the pharmacy claims system charging a brand copayment (the generic copayment for DMHC governed plans and the Brand, the Non-preferred copay or Specialty copay (if the drug is a Specialty Drug) copayment for CDI governed plans) plus the difference between the Brand and the generic (MAC'd) price.

The MAC U option only allows single source and narrow therapeutic index Brands to process at the tier displayed on the Formulary. If the Branded product has a generic equivalent or is not listed on the Formulary, prior approval demonstrating medical necessity is required to obtain the drug. If no authorization the drug is not covered under this benefit.

Generic Drugs are 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 for Health Net health plans 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.

Policy/Criteria

I. It is Health Net of California's policy that generic drugs will be used whenever a Brand is prescribed. There are different drug substitution programs and benefits that must be considered before requiring prior approval for a Brand over a generic.

II. It is the policy of health plans affiliated with Centene Corporation® that non-preferred brand name drugs may be approved when they are **medically necessary.** *Providers must submit*

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

III. Medical Necessity must ensure the following criteria are met:

A. Initial Approval Criteria - Request for Brand Name Drug in Lieu of Generic Formulation (must meet all)**:**

1. Failure of an adequate trial of or clinically significant adverse effects to 2 generics* or the preferred biosimilar(s) of the requested brand name drug, each from a different manufacturer, unless member is contraindicated to the excipients in all generics/biosimilars;
   **If a second generic of the requested brand name drug is not available, member must try a preferred generic drug from a similar therapeutic class (e.g., meloxicam for Naprosyn), provided that such agent exists.*
   a) Examples of failure of a generic drug include:
      i. Suboptimal drug plasma levels while taking the generic drug as compared to drug plasma levels while taking the brand name drug;
      ii. 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.
2. If an authorized generic is available, must use the authorized generic*.
   ***FDA List of Authorized Generic Drugs**
   https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs
3. If clinically significant adverse effects were experienced, provider submits a copy of the MedWatch form(s) submitted to the FDA;
   a) MedWatch forms can be obtained and completed online at the FDA website. They can also be requested by contacting Envolve Pharmacy Solutions via phone (1800-460-8988) or fax (1-866-399-0929).
   b) Sections A, B, D, and G are to be completed by the prescriber.
4. 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;
5. Dose does not exceed the FDA approved maximum recommended dose.
6. The use of a copay card or other copay offset programs is **not** an accepted reason for approving a Brand over the generic.

Approval duration: 12 months

B. Other drugs:

1. Brand drugs with a narrow therapeutic index (NTI) may be listed on the Formulary at a higher tier and do not require prior approval. NTI drugs include:
   a) Drugs for the treatment of Epilepsy
   b) Drugs for the treatment of hypothyroidism

(See https://go.drugbank.com/categories/DBCAT003972 for a more extensive list of NTI drugs)

Approval duration: 12 months

IV. Continued Therapy

A. Request for Brand Name Drug in Lieu of Generic Formulation

If the drug was approved for coverage prior to the generic being available, the generic form will continue to be covered. A "Brand request" for a previously approved drug will require ALL of the following [Refer to HSC § 1367.22 … nor shall anything in this section be construed to prohibit generic drug substitutions as authorized by Section 4073 of the Business and Professions Code]:

1. Currently receiving medication under a Health Net benefit;
2. Member has previously met approval criteria stated in section III above;
3. Member is responding positively to therapy;
4. If request is for a dose increase, the new dose does not exceed the FDA approved maximum recommended dose.

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable

V. Generic drugs not available in the Market place

A. Brand Drugs that are requested due to the generic equivalent not being available may be approved on a one-time basis.

1. Temporary manufacturing problems
2. Manufacturer backorder

B. Brands approved due to unavailability of the generic will be at the applicable tier copay (Brand, Non-preferred, or Specialty).

C. Approval for a Brand due to unavailability in the market place means that there is a wide spread shortage to all pharmacies and multiple drug wholesalers. It does **not** include:

1. The pharmacy is out of stock
2. The pharmacy's wholesaler is out of stock

VI. Ancillary Fees/Product Selection Penalty Overrides

A. For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

B. For MAC A plans that are regulated by the Department of Managed Health Care (DMHC) only, the Product Selection Penalty or Ancillary fee (difference in cost between the brand and the generic drug) may be waived:

1. if there is the option to waive the ancillary charge indicated in the Member's EOC and,
2. the physician specifically requests the ancillary charge to waived and,
3. medical necessity is met

C. If approved, the member will be charged the applicable tier copay for the branded product depending on the Formulary.

1. If a Specialty drug copayment override is approved it shall be at the highest Tier (e.g. Specialty Tier)
2. Enrollees using a copay card or other copay offset programs are **not eligible for a**

copay override.

D. For MAC U plans copay overrides will be at the non-preferred tier (Tier 3) or Specialty Tier for drugs over $600.

VII. Diagnoses/Indications for which coverage is NOT authorized:

Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies –CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

VIII. References

1. FDA Center for Drug Evaluation and Research (CDER) Orange Book Preface at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Accessed July 3 2023.
2. FDA Electronic Orange Book at http://www.fda.gov/cder/ob/. Accessed July 3, 2023.
3. FDA MedWatch Reporting Forms at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm. Accessed July 3, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy.	11.1.18	01.19
Updated Section IV.A. Request for Brand Name Drug in Lieu of Generic Formulation, to further clarify how to handle a situation where a drug was previously approved for coverage prior to a generic being available.	02.20.20	04.14.20
1Q 2022 annual review: Removed the following statement from section III initial approval criteria part B "If a drug in one of these NTI classes is approved through prior authorization the approval duration is open-ended" and added the approval duration of 12 months to this section.; Health Net new logo added; Diagnoses/Indications for which coverage is NOT authorized added; references reviewed and updated.	10.18.21	01.22
Annual review. Under III A: added biosimilar to (1) and inserted the need to use an authorized generic if available under (2). Added a reference (*https://go.drugbank.com/categories/DBCAT003972)* for a more complete list of narrow therapeutic index drugs, under section III.B. Updated references.	6.23.23	07.11.23

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

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This clinical policy is effective as of November 1, 2018. 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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