

HPHC CUSTOM PRIOR AUTHORIZATION EXCEPTION CRITERIA

POLICY

I. PROGRAM SUMMARY

Section One:

The Dosage Exception Criteria ensure appropriate utilization of medications managed through the CVS Novologix program and confirm that requests for dosing regimens outside FDA-approved product labeling are handled efficiently and consistently. This policy applies to medication dosages not otherwise managed through a product-specific Specialty Guideline Management (SGM) program. The criteria may be applied in situations where specific criteria or criteria updates are pending development and configuration.

The coverage criteria confirm the dosage is evaluated using the following criteria provided by HPHC to evaluate cases outside of current approved SGM criteria.

Section Two:

New FDA label indications for drugs in the Novologix program may be approved for new FDA covered indication, dose, and frequency for up to 12 months while waiting policy development if two other approved therapies (when available) for the indication have been tried and failed or are contraindicated.

II. CRITERIA FOR APPROVAL

Section One:

Authorization for the same duration as noted in the drug-specific policy may be granted for a requested medication dosage that exceeds the FDA-approved dosing regimen when all of the following criteria are met:

1. Member achieved a suboptimal response with a dose prescribed within the FDA-approved dosing regimen
2. Requested dosing regimen is supported by ONE of the following:
 - a. Medically accepted compendia or National Guidelines
 - b. Clinical evidence from at least one peer-reviewed journal article submitted by the provider
 - c. Established member is stable on the requested dose or the provider indicates it is medically necessary, either of which is confirmed in clinical documents submitted by the provider. A supporting statement along is not considered sufficient information for an exception.

Section Two:

Authorization up to 12 months may be granted for an FDA-approved medication with a newly approved indication not currently included in the drug-specific policy when all of the following criteria are met:

1. Request is for an FDA-approved indication
2. At least two alternative therapies for the same indication, when available, have been tried and failed or are contraindicated
3. If there are additional requirements listed in the "Indications and Usage" section of the prescribing information (e.g., first line therapies, testing requirements, etc.), they have been met

4. The requested dosing regimen does not exceed the FDA-approved dosing regimen

Limitations:

1. The duration of coverage will be limited to 12 months, or up to a complete course of therapy if less than one year as noted in the medication's FDA-approved prescribing information, or as deemed clinically necessary.
2. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

General Guidelines for Medical Directors:

1. For questions or concerns the CVS medical director may contact HPHC senior medical director for guidance.