Zyflo®/Zyflo CR (zileuton)

Policy # 00529
Original Effective Date: 01/01/2017
Current Effective Date: 01/01/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider Zyflo®/Zyflo CR (zileuton) to be eligible for coverage when the patient selection criterion is met.

Patient Selection Criteria
Coverage eligibility for Zyflo/Zyflo CR (zileuton) will be considered when the following criterion is met:

- Patient has tried and failed (e.g. intolerance or inadequate response) at least TWO generic leukotriene inhibitors (e.g. montelukast, zafirlukast) unless there is clinical evidence or patient history that suggests at least TWO generic leukotriene inhibitors (e.g. montelukast, zafirlukast) will be/was ineffective or will/did cause an adverse reaction to the patient

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Zyflo/Zyflo CR (zileuton) WITHOUT evidence that the patient has tried and failed at least TWO generic leukotriene inhibitors (e.g. montelukast, zafirlukast) to be not medically necessary.**

Background/Overview
Zyflo and Zyflo CR are both leukotriene synthesis inhibitors that are approved for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. There are various alternative generic options (with a similar mechanism of action) including montelukast and zafirlukast that are a much more economical option. These generic options either include more indications or a more broad age range than Zyflo or Zyflo CR offer.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
Zyflo was approved in 1996 and Zyflo CR was approved in 2007. Both carry the same indication, which is for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. The generic products, montelukast and zafirlukast, collectively include expanded indications as well as broader age ranges.

Rationale/Source
The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests TWO generic leukotriene inhibitors (e.g. montelukast, zafirlukast) will be/was
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ineffective or will/did cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using Zyflo/Zyflo CR (zileuton) over TWO generic leukotriene inhibitors (e.g. montelukast, zafirlukast).

References

Policy History

Original Effective Date: 01/01/2017
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09/08/2016  Medical Policy Committee review
09/21/2016  Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 09/2017

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.