Helidac® (bismuth subsalicylate, metronidazole, tetracycline)

Policy # 00745
Original Effective Date: 05/10/2021
Current Effective Date: 05/10/2021

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 Helidac®‡ (bismuth subsalicylate, metronidazole, tetracycline) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Helidac (bismuth subsalicylate, metronidazole, tetracycline) will be considered when the following criteria are met:

- Patient has an *H. pylori* infection and the presence of duodenal ulcer disease; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following agents: Omeclamox™‡ (omeprazole, clarithromycin, amoxicillin), Pylera®‡ (bismuth subcitrate, metronidazole, tetracycline), Talicia®‡ (omeprazole, amoxicillin, rifabutin), or GENERIC combination lansoprazole, amoxicillin, clarithromycin (Prevpak®)‡ unless there is clinical evidence or patient history that suggests the use of these agents will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Helidac (bismuth subsalicylate, metronidazole, tetracycline) when the patient has not tried and failed TWO of the following agents: Omeclamox (omeprazole, clarithromycin, amoxicillin), Pylera (bismuth subcitrate, metronidazole,

tetracycline), Talicia (omeprazole, amoxicillin, rifabutin), or GENERIC combination lansoprazole, amoxicillin, clarithromycin (Prevpak) to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Helidac (bismuth subsalicylate, metronidazole, tetracycline) for any indication other than the treatment of *H. pylori* infection and the presence of duodenal ulcer disease to be **investigational.***

Background/Overview

Helidac is indicated for the eradication of *H. pylori* for treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or a history of duodenal ulcer). Helidac has been available on the market intermittently and is currently available again at the time of this publication. The choice of antibiotic regimen for the treatment of *H. pylori* infections should be guided by risk factors for macrolide resistance and the presence/absence of a penicillin allergy. Risk factors for macrolide resistance include prior exposure to a macrolide for any reason OR a high local clarithromycin resistance rate ≥15% or eradication rates with clarithromycin triple therapy ≤85%. In patients without risk factors for macrolide resistance, a triple therapy regimen consisting of a proton pump inhibitor (PPI), amoxicillin, and clarithromycin should be used. Amoxicillin should be substituted with metronidazole in patients with a penicillin allergy. In patients with risk factors for macrolide resistance, quadruple therapy with bismuth, a proton pump inhibitor, and two antibiotics (metronidazole and tetracycline) should be given. Talicia is another product that is available for patients with risk factors for macrolide resistance. Treatment with these regimens typically lasts for 14 days. It is possible to take these products individually, however there are FDA approved combination drugs packaged together for this specific use. Helidac therapy is another option in a long line of options for the treatment of *H. pylori* and other products on the market offer a more economically advantageous and equally effective option for therapy. Helidac is approved by the FDA for use in combination with an H_2 antagonist, but H_2 antagonists are no longer recommended for the treatment of *H. pylori*. Helidac offers no advantages over the currently available products on the market.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Helidac, in combination with an H_2 antagonist, is indicated for the eradication of *H. pylori* for treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or a history of duodenal ulcer).

Rationale/Source

The purpose of this policy is to ensure that the requested drug is used per the FDA approved indication and that the most efficacious and cost-effective regimens are used for the requested condition.

References

1. Helidac [package insert]. Casper Pharma LLC. Updated August 2019.
2. Treatment regimens for *H. pylori.* UpToDate. Accessed March 2021.

Policy History

Original Effective Date: 05/10/2021
Current Effective Date: 05/10/2021
04/01/2021 Medical Policy Committee review
04/14/2021 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 04/2022

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety,

effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.