## PROVIDER BULLETIN PROVIDER INFORMATION



December 2, 2015

## Prior Authorization Requirements for a New Drug, Obeticholic Acid

Blue Cross and Blue Shield of Minnesota (Blue Cross) will require prior authorization (PA) for a new drug, obeticholic acid (Brand name not yet known). This PA requirement will become effective February 29, 2016, pending the release of FDA-approved indications for this drug.

Obeticholic acid (Brand name not yet known) is a drug anticipated to be approved for use in combination with ursodeoxycholic acid (UDCA) = ursodiol; for treatment of primary biliary cirrhosis in adults with inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Obeticholic acid (Brand name not yet known) is expected to be approved by the FDA on or after February 29, 2016.

As stewards of healthcare expenditures for our subscribers, we are charged with ensuring the highest quality, evidence based care for our members. One method for doing so is through the PA process. The primary purpose is to ensure that evidence based care is provided to our members, driving quality, safety, and affordability.

The intent of this PA is to ensure appropriate selection of patients for treatment according to FDA approved product labeling. The obeticholic acid (Brand name not yet known) PA defines appropriate use as use in patients who have an FDA approved indication, who are receiving the FDA labeled dose, and who do not have any FDA labeled contraindications. Requests will be reviewed when patient-specific documentation has been provided.

## **Products impacted**

This PA program applies to commercial lines of business.

Drug-specific PA criteria will be developed and posted after FDA-approved indications are released, and can be accessed using the Blue Cross provider link.

- Access providers.bluecrossmn.com
- Under Tools And Resources, select Medical policy, then acknowledge the Acceptance statement
- Select Utilization Management
- Select Pharmacy Utilization Management

## Questions?

If you have questions, please contact provider services at (651) 662-5200 or 1-800-262-0820.