Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Givlaari (givosiran)

Override(s)	Approval Duration
Prior Authorization	Initial Requests: 6 months Maintenance Requests: 12 months

Medications
Givlaari (givosiran)

APPROVAL CRITERIA

Requests for initiation of Givlaari (givosiran) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of acute hepatic porphyria, **and** confirmation of one of the following subtypes (APF 2010-2019):
    a. Acute intermittent porphyria (AIP); **OR**
    b. Hereditary coproporphyria (HCP), **OR**
    c. Variegate porphyria (VP); **OR**
    d. ALA dehydratase-deficiency porphyria (ADP); **AND**
III. Individual has documentation of elevated urinary or plasma porphobilinogen (PBG) or delta-aminolevulinic acid (ALA) within the past year (NCT03338816); **AND**
IV. Individual has active symptomatic disease, with at least two documented porphyria attacks within the last six months (NCT03338816).

Requests for continuation of Givlaari (givosiran) may be approved if the following criteria are met:

I. Individual has experienced a clinical response to therapy (for example, a reduction in the number of porphyria attacks); **AND**
II. Individual does not have severe or clinically significant transaminase elevations, defined as alanine aminotransferase (ALT) greater than 5 times the upper limit of normal (Balwani 2019).

Givlaari (givosiran) may not be approved for the following (NCT03338816):

I. Liver transplantation is anticipated; **OR**
II. Individual has a history of recurrent pancreatitis; **OR**
III. Individual is requesting for other forms of porphyria, such as cutaneous porphyrias (for example, porphyria cutanea tarda [PCT]); **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

IV. When the above criteria are not met and for all other indications.

Key References:

1. Balwani M, Gouya L, Rees DC, et al. ENVISION, a Phase 3 Study to Evaluate the Efficacy and Safety of Givosiran, an Investigational RNAi Therapeutic Targeting Aminolevulinic Acid Synthase 1, in Acute Hepatic Porphyria Patients. April 13, 2019. European Association for the Study of the Liver (EASL) 54th Annual International Liver Congress. Vienna, Austria.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: November 22, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
6. NCT03338816. ClinicalTrials.gov. U.S. National Library of Medicine. Available at https://clinicaltrials.gov/ct2/show/NCT03338816?term=nct03338816&draw=1&rank=1. Accessed on November 22, 2019.
7. Porphyria. American Porphyria Foundation (APF). 2010-2019. Available at https://www.porphyriafoundation.org/for-healthcare-professionals/porphyria/. Accessed on November 26, 2019.
8. The Porphyrias Consortium. Rare Diseases Clinical Research Network. National Institutes of Health. Available at https://www.rarediseasesnetwork.org/cms/porphyrias/Healthcare-Professionals/Disorder-Definitions. Accessed on November 26, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.