AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Recorlev			Page:	1 of 2
Effective Date:	8/19/2024			Last Review Date:	7/2024
Applies to:	☒Illinois ☒New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☒Virginia		☒Florida Kids ☐Michigan ☐Texas	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Recorlev under the patient's prescription drug benefit.

Description:

Recorlev is indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.

Limitations of Use: Recorlev is not approved for the treatment of fungal infections. The safety and effectiveness of Recorlev for the treatment of fungal infections have not been established.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Non-Formulary Drug: Recorlev

Policy/Guideline:

Cushing's Syndrome/Disease

Criteria for Initial Approval:

I. Submission of the following information is necessary to initiate the prior authorization review:
   A. Pretreatment cortisol level as measured by one of the following tests:
      1. Urinary free cortisol (UFC)
      2. Late-night salivary cortisol
      3. 1 mg overnight dexamethasone suppression test (DST)
      4. Longer, low dose DST (2 mg per day for 48 hours)
   B. For treatment of endogenous hypercortisolemia in adult members with Cushing's syndrome/disease who have either had surgery that was not curative OR for members who are not candidates for surgery.

Continuation of Therapy:

II. Continuation of therapy may be granted for endogenous hypercortisolemia in adult members with Cushing's syndrome/disease, who are currently receiving the requested medication and who meet one of the following:
   A. Lower cortisol levels since the start of therapy per one of the following tests:

1. Urinary free cortisol (UFC)
2. Late-night salivary cortisol
3. 1 mg overnight dexamethasone suppression test (DST)
4. Longer, low dose DST (2 mg per day for 48 hours)

B. Improvement in signs or symptoms of the disease

Approval Duration and Quantity Restrictions:

Initial Approval: 6 months

Renewal Approval: 12 months

Quantity Level Limit: 240 tablets per 30 days

References:

1. Recorlev [package insert]. Chicago, IL: Xeris Pharmaceuticals, Inc.; May 2023.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818
3. Fleseriu M, Auchus R, Bancos I, et al. Consensus on diagnosis and management of Cushing's disease: a guideline update. *Lancet Diabetes Endocrinol*. 2021;9(12):847-875. doi:10.1016/S2213-8587(21)00235-7