

Clinical Oversight Review Board (CORB) Criteria for Prescribing Elivaldogene Autotemcel (Skysona)

Notes:

- ^ Diagnosis of active CALD as defined by:
 - Elevated very long chain fatty acids (VLCFA) values; and
 - Active central nervous system (CNS) disease established by central radiographic review of brain MRI demonstrating:
 - Loes score between 0.5 and 9 (inclusive) on the 34-point scale; and
 - Gadolinium enhancement on MRI of demyelinating lesions

Non-Formulary **elivaldogene autotemcel (Skysona)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria:

- Prescribed by a Pediatric Neurology or Pediatric Hematology/Oncology Specialist
- Patient has a diagnosis of active cerebral adrenoleukodystrophy (CALD)^
- Patient is male **AND** is 4 years old to 17 years old
- Patient has a neurologic function score (NFS) of 1 or less
- Patient has not had a previous bone marrow transplant
- Patient does not have an available human leukocyte antigen (HLA)-matched donor for allogeneic hematopoietic stem cell transplant
- Patient has not previously used (elivaldogene autotemcel) Skysona. Repeat dosing has not been studied and is not recommended
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication