06/29/2023

HHSC to Add Skysona as Medicaid and CHIP Benefit July 1, Prior Authorization Effective Sept. 1

Background:

On July 1, 2023, Skysona will become a benefit of Medicaid and CHIP. HHSC will require prior authorization for Skysona (procedure code J3590) for Medicaid and CHIP effective Sept. 1, 2023.

Key Details:

Authorization requirements

Prior authorization is required for Skysona (elivaldogene autotemcel). The request for this single-dose therapy must include all the following documentation to support client meets all approval criteria:

- Client is a male between the ages of 4 years to 17 years.
- Client has a documented diagnosis of cerebral adrenoleukodystrophy (ICD 10 – E71.511, E71.520, E71.521, E71.528, and E71.529)
- Client has a variant in the ABCD1 gene as evident by a genetic test.
- Client's CALD is caused by the presence of a variant of the ABCD1 gene causing elevated very long fatty acid (VLCFA) and not secondary to head trauma.
- Client has early, active CALD as defined by all the following:
    - Client is asymptomatic or mildly symptomatic with neurologic function score (NFS) of less than or equal to 1; **AND**
    - Client has gadolinium enhancement on brain magnetic resonance imaging (MRI); **AND**
    - Client has a Loes score ranging from 0.5 to 9.
- Client has not had hematopoietic stem cell transplant (HSCT), is eligible for HSCT, and is unable to find a matched related donor
- Client's screening result is negative for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) and Human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2) prior to the collection of cells for manufacturing.
- Prescriber must attest to monitor clients closely for evidence of life-threatening hematological malignancy through complete blood count (CBC) at least every six months and through assessment for possible clonal expansion a least twice in the first year and annually thereafter.
- Prescriber must attest to monitor client for signs of bleeding and infections after the treatment with Skysona as life threatening bacterial/viral infection may occur as well as thrombocytopenia and prolonged cytopenia.
- Client must avoid taking anti-retroviral medications for at least one month prior to initiating medication for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are complete.
- Skysona (elivaldogene autotemcel), J3590 is limited to one transfusion treatment per lifetime.

Refer to the Outpatient Drug Services Handbook Chapter of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

Additional Information:

HHSC approved this updated clinical prior authorization for use by Managed Care Organizations (MCOs). FFS criteria will implement on Sept. 1, 2023. MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but shall not make them more restrictive.

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Type: Informational

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From: VDP