CADTH Evidence Driven.

onasemnogene abeparvovec

Last Updated:

March 26, 2021

Result type:

Reports

Project Number:

SG0649-000

Product Line:

Reimbursement Review

Generic Name: onasemnogene abeparvovec

Brand Name: Zolgensma

Manufacturer: Novartis Pharmaceuticals Canada Inc.

Therapeutic Area: Spinal muscular atrophy (SMA), pediatrics

Indications: Zolgensma is an adeno-associated virus (AVV) vector-based gene therapy indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene.

Manufacturer Requested Reimbursement Criteria[1]: Zolgensma is an adeno-associated virus (AVV) vector-based gene therapy indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene

Submission Type: Initial

NOC Status at Filing: Pre NOC

Project Status: Active

Companion Diagnostics: No

Date Recommendation Issued: March 24, 2021

Recommendation Type: Reimburse with clinical criteria and/or conditions

Fee Schedule: Schedule E

1. The requested reimbursement criteria are provided by the applicant and do not necessarily reflect the views of CADTH. Reimbursement criteria from CADTH will be documented in the final recommendation, if applicable.

Key Milestones

Call for patient input open	May 26, 2020
Call for patient input closed **Clarification:** - Patient input submission received from Cure SMA Canada and Muscular Dystrophy Canada (MDC)	July 15, 2020
Submission received	June 25, 2020
Submission accepted	July 10, 2020
Review initiated **Clarification:** - Selected for CADTH/INESSS Joint Clinician Engagement	July 13, 2020
Draft CADTH review report(s) provided to sponsor for comment	September 29, 2020
Deadline for sponsors comments	October 08, 2020
CADTH responses on draft review report(s) provided to sponsor	November 06, 2020
Expert committee meeting (initial)	November 18, 2020
Draft recommendation issued to sponsor	December 17, 2020
End of embargo period **Clarification:** - Request for extension to feedback period received from the sponsor - Feedback extension request granted - Reconsideration requested - Request for Clarification received from DRR Participating Drug Plans	February 05, 2021
Expert committee meeting	March 17, 2021
Final recommendation issued to sponsor and drug plans	March 24, 2021

Key Milestones

Final recommendation posted	March 26, 2021
Deadline for sponsor to submit redaction requests on draft CADTH review report(s)	April 08, 2021
CADTH review report(s) posted	

Files

Recommendation and Reasons

Patient Group Input Submission