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CADTH Evidence Driven.

nitisinone

Last Updated:

April 30, 2018

Result type:

Reports

Project Number:

SR0538-000

Product Line:

Common Drug Review

Generic Name: nitisinone

Brand Name: MDK-Nitisinone

Manufacturer: MendeliKABS Inc

Indications: Hereditary tyrosinemia type 1

Project Status: Complete

Biosimilar: No

Date Recommendation Issued: April 25, 2018

Recommendation Type: Reimburse with clinical criteria and/or conditions

Fee Schedule: Schedule A

Key Milestones

Call for patient input posted	August 31, 2017
Patient group input closed	October 23, 2017

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Key Milestones

Clarification:
- Patient input submission received

Submission received	September 29, 2017
Submission accepted for review	October 16, 2017
Review initiated	October 20, 2017
Draft CDR review report(s) sent to applicant	January 24, 2018
Comments from applicant on draft CDR review report(s) received	February 02, 2018
Redaction requests from applicant on draft CDR review report(s) received	February 09, 2018
Canadian Drug Expert Committee (CDEC) meeting	March 21, 2018
CDEC recommendation & redacted CDR review report(s) sent to applicant and drug plans	April 04, 2018
Embargo period ended and validation of redacted CDR review report(s) received	April 18, 2018
CDEC Final Recommendation issued to applicant and drug plans	April 25, 2018
CDEC Final Recommendation posted	April 27, 2018
Final CDR review report(s) and patient input posted	April 27, 2018

Tags

digestive system, genetics, pediatrics, tyrosinemias, nitisinone; tyrosinemia

Files

Recommendations and Reasons

Clinical Report

Pharmacoeconomic Report

Patient Group Input Submissions

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