Clinical Policy Title:	elbasvir/grazoprevir
Policy Number:	RxA.572
Drug(s) Applied:	Zepatier®
Original Policy Date:	03/06/2020
Last Review Date:	7/19/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Chronic Hepatitis C Infection: Genotype 1a WITH baseline NS5A resistance-associated polymorphisms (must meet all):

1. Member meets one of the following (a or b):
   a. Treatment-naïve;
   b. Failed prior treatment with PegIFN and RBV with or without an HCV protease inhibitor (e.g., boceprevir, simeprevir or telaprevir);
2. Member has a baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93);
3. Used in combination with Ribavirin;
4. Trial and failure, intolerance, or contraindication to the following (must meet a and b)
   a. sofosbuvir/velpatasvir or ledipasvir/sofosbuvir;
   b. Mavyret;
5. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV.

Approval duration
All Lines of Business (except Medicare): 4 months

B. Chronic Hepatitis C Infection: Genotype 1a WITHOUT baseline NS5A resistance-associated polymorphisms (must meet all):

1. Member meets one of the following (a, b, or c):
   a. Treatment-naïve;
   b. Failed prior treatment with PegIFN and RBV;
   c. Failed prior treatment with PegIFN and RBV with HCV protease inhibitor (e.g., boceprevir, simeprevir or telaprevir) AND will be used in combination with Ribavirin;
2. Member has been tested and does not have NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93);
3. Trial and failure, intolerance, or contraindication to the following (must meet a and b)
   a. sofosbuvir/velpatasvir or ledipasvir/sofosbuvir;
   b. Mavyret;
4. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV.

Approval duration
All Lines of Business (except Medicare): 4 months

C. Chronic Hepatitis C Infection: Genotype 1b (must meet all):
1. Member meets one of the following (a, b, or c):
   a. Treatment-naïve;
   b. Failed prior treatment with PegIFN and RBV;
   c. Failed prior treatment with PegIFN and RBV with HCV protease inhibitor (e.g., boceprevir, simeprevir or telaprevir) AND will be used in combination with Ribavirin;
2. Trial and failure, intolerance, or contraindication to the following (must meet a and b)
   a. sofosbuvir/velpatasvir or ledipasvir/sofosbuvir;
   b. Mavyret;
3. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV.

Approval duration
All Lines of Business (except Medicare): 4 months

D. Chronic Hepatitis C Infection: Genotype 4 (must meet all):
1. Member meets one of the following (a or b):
   a. Treatment-naïve;
   b. Failed prior treatment with PegIFN and RBV AND will be used in combination with Ribavirin;
2. Trial and failure, intolerance, or contraindication to the following (must meet a and b)
   a. sofosbuvir/velpatasvir or ledipasvir/sofosbuvir;
   b. Mavyret;
3. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV.

Approval duration
All Lines of Business (except Medicare): 4 months

II. Continued Therapy Approval

A. Chronic Hepatitis C Infection:
1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.
2. Member requires an additional course of therapy per FDA or AASLD IDSA guidelines.
   All lines of business (except Medicare): 3 months

References

1. American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA). HCV guidance: recommendations for testing, managing, and treating hepatitis C. Last updated October 24, 2022. Available at: https://www.hcvguidelines.org/. Accessed January 01, 2024.
2. Bonder A, Afdhal N. Utilization of FibroScan in clinical practice. *Curr Gastroenterol Rep*. 2014;16(2):372. Available at: https://pubmed.ncbi.nlm.nih.gov/24452634/. Accessed January 01, 2024.
3. Halfon P, Bourliere M, Deydier R, et al. Independent prospective multicenter validation of biochemical markers (Fibrotest-actitest) for the prediction of liver fibrosis and activity in patients with chronic hepatitis C: the fibropaca study. Am J Gastroenterol. 2006;101(3):547-55. Available at: https://pubmed.ncbi.nlm.nih.gov/16542291/. Accessed January 01, 2024.

4. Hsieh Y-Y, Tung S-Y, Lee K, et al. Routine blood tests to predict liver fibrosis in chronic hepatitis C. World J Gastroenterol. 2012;18(8):746-753. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3286137/. Accessed January 01, 2024.
5. Terrault NA, Bzowej NH, Chang K-M, Hwang JP, Jonas MM, Murad MH. AASLD guidelines for treatment of chronic hepatitis b. Hepatology. 2016;63(1):261-283. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5987259/. Accessed January 01, 2024.
6. Foster GR, Agarwal K, Cramp ME, et al. Elbasvir/grazoprevir and sofosbuvir for hepatitis C virus genotype 3 infection with compensated cirrhosis: A randomized trial. Hepatology. 2018;67(6):2113-2126. Available at: https://pubmed.ncbi.nlm.nih.gov/29473975/. Accessed January 01, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established	01/2020	03/06/2020
1. Policy was reviewed: 2. Clinical Policy Title Table was updated. 3. Line of business policy applies was updated to All lines of business. 4. Initial criteria for approval updated specific to genotype. 5. Continued Therapy criteria II.A.1 was rephrased to " Member is currently receiving medication that has been authorized by RxAdvance..." 6. Initial Approval criteria: Commercial and Medicaid approval duration updated. 7. Continued Approval criteria: Commercial and Medicaid approval duration were updated from up to total of 16 weeks to 112 days. 8. References were reviewed and updated.	10/07/2020	12/07/2020
Policy was reviewed: 1. Continued Therapy Approval II.1 was reframed to "Member is currently receiving medication.." 2. Continued Therapy Approval II.2 was reframed to "Member must meet both of the following..." 3. References were reviewed and updated.	10/08/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated age criteria from Age ≥ 18 years to Age ≥ 12 years or weighing at least 30 kg. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	02/16/2022	04/18/2022

Policy was reviewed: 1. References were reviewed and updated.	01/20/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Updated to separate Chronic Hepatitis C Infection indication to four different criteria as: a. Genotype 1a WITH baseline NS5A resistance-associated polymorphisms (must meet all) b. Genotype 1a WITHOUT baseline NS5A resistance-associated polymorphisms (must meet all) c. Chronic Hepatitis C Infection: Genotype 1b. d. Chronic Hepatitis C Infection: Genotype 4. 2. Removed requesting (documentation) criteria. 3. Removed prior dosing criteria. 4. Removed reauthorization requirement for positive response to therapy. 5. References were reviewed and updated.	01/01/2024	01/01/2024
Policy was reviewed: 1. Revised continued therapy approval to be subject to initial criteria based on review. 2. Extended the duration of approval for each indication to 4 months	7/19/2024	7/19/2024