Clinical Policy Title:	dasabuvir/ombitasvir/paritaprevir/ritonavir
Policy Number:	RxA.550
Drug(s) Applied:	Viekira Pak®
Original Policy Date:	03/06/2020
Last Review Date:	07/19/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Chronic Hepatitis C (CHC) Infection (must meet all)**:**

1. Diagnosis of chronic hepatitis C (CHC) genotype 1;
2. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or a liver transplant physician;
3. If the member has liver cirrhosis, cirrhosis is compensated or Child-Pugh A status;
4. Member has tried and failed sofosbuvir/velpatasvir,unless contraindicated or clinically significant adverse effects are experienced;
5. If HCV/HIV-1 co-infection, member is or will be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance;
6. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen;

Approval Duration

All lines of business (except Medicare): 3 months

II. Continued Therapy Approval

1. **A. Chronic Hepatitis C Infection** 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.

Approval Duration

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 September 29, 2021. Available at: https://www.hcvguidelines.org/. Accessed September 19, 2022.
2. CDC. Hepatitis C Q&As for health professionals. Last updated August 7, 2020. Available at: https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm. Accessed September 19, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date

Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Initial approval criteria I.A.6 updated to limit try and fail products to Epclusa and Harvoni and to reflect use of brand over generic due to rebates available. 3. References were updated.	11/24/2020	12/07/2020
Policy was reviewed: 1. Approval durations were updated from 12 weeks to 3 months. 2. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. Viekira XR is discontinued. Information pertaining to it removed throughout the policy. 4. References were reviewed and updated.	10/02/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.3: Updated prescriber criteria from Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease physician to Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease specialist or a liver transplant physician. 2. Initial Approval Criteria, I.A.6: Updated trial and failure criteria from Member must use Harvoni® (brand preferred over generic) or Epclusa® (brand preferred over generic) unless contraindicated or clinically significant adverse effects are experienced to Member must use Epclusa® unless contraindicated or clinically significant adverse effects are experienced. *Coadministration with omeprazole up to 20 mg is not considered acceptable	09/19/2022	10/19/2022

medical justification for inability to use Epclusa. 3. Initial Approval Criteria, 1.A.7: Updated to include new criteria pertaining to indication Chronic Hepatitis C Infection, Life expectancy ≥ 12 months with HCV treatment. 4. Initial Approval Criteria, 1.A.8: Updated to include new Medication adherence program criteria a. Medication adherence monitored by pharmacy claims data or member report; b. Member's risk for non-adherence identified by adherence program or member/prescribing physician follow-up at least every 4 weeks; 5. Continued Therapy Approval, II.A.1.b.i: Updated documentation criteria from Documentation supports that member is currently receiving Viekira Pak® for chronic HCV infection and has recently completed at least three quarters of the full regimen with Viekira Pak® to Documentation supports that member is currently receiving Viekira Pak® for chronic HCV infection and has recently completed at least 60 days of treatment with Viekira Pak®. 6. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Police was reviewed: Initial Approval 1. Removed diagnosis confirmation by assay. 2. Revised language for compensated cirrhosis.	7/19/2024	7/19/2024

3. Revised criteria for trial and failure of generic Epclusa (sofosbuvir/velpatasvir). 4. Removed life expectancy criteria. 5. Removed age requirement. 6. Removed participation in a medication adherence program. 7. Removed dosing. Continued Approval 1. Removed authorization by RxAdvance. 2. Removed confirmation of continuation of therapy and genotype criteria. 3. Removed responding positively to therapy. 4. Removed dosing.		