**Infectious Disease Agents: Antivirals – Hepatitis C Agents**

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria Title** | Infectious Disease Agents: Antivirals – Hepatitis C Agents | | |
| **Criteria Subtitle** | All Products | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred |  | | Non-Preferred |  | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| HARVONI | 072926 | GCNSeqNo |
| HARVONI | 080162 | GCNSeqNo |
| HARVONI | 080179 | GCNSeqNo |
| HARVONI | 080180 | GCNSeqNo |
| LEDIPASVIR/  SOFOSBUVIR | 072926 | GCNSeqNo |
| MAVYRET | 077637 | GCNSeqNo |
| MAVYRET | 082438 | GCNSeqNo |
| PEGASYS | 050736 | GCNSeqNo |
| PEGASYS | 051151 | GCNSeqNo |
| RIBAVIRIN | 048664 | GCNSeqNo |
| RIBAVIRIN | 051637 | GCNSeqNo |
| RIBAVIRIN | 060100 | GCNSeqNo |
| SOFOSBUVIR/VELPATASVIR | 076305 | GCNSeqNo |
| SOFOSBUVIR/VELPATASVIR | 081610 | GCNSeqNo |
| SOFOSBUVIR/VELPATASVIR | 082395 | GCNSeqNo |
| SOFOSBUVIR/VELPATASVIR | 082396 | GCNSeqNo |
| SOVALDI | 071748 | GCNSeqNo |
| SOVALDI | 080163 | GCNSeqNo |
| SOVALDI | 080164 | GCNSeqNo |
| SOVALDI | 080165 | GCNSeqNo |
| VOSEVI | 077584 | GCNSeqNo |
| ZEPATIER | 075514 | GCNSeqNo |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sequence Number** | **Question ID** | **Default Next Question ID** | **Question Type** | **Question Text** | **Choice Text** | **Next Question ID** |
| 1 | 1000 |  | Select and Free Text | Has the provider submitted documentation of the patient’s active HCV infection verified by viral load within 180 days (HCV RNA value and date)?  If yes, please enter the HCV RNA count (million IU/mL) and date of verification. | Y | 1001 |
| N | 1235 |
| 2 | 1001 |  | Select and Free Text | Has the provider submitted documentation of the patient’s HCV genotype (verified by lab genotype)?  If yes, please submit documentation. | Y | 1002 |
| N | 1235 |
| 3 | 1002 |  | Select | What is the patient’s genotype? | 1a | 1003 |
| 1b | 1003 |
| 2 | 1003 |
| 3 | 1003 |
| 4 | 1003 |
| 5 | 1003 |
| 6 | 1003 |
| Other | 1235 |
| 4 | 1003 |  | Select and Free Text | Has the provider submitted documentation of the patient’s hepatitis fibrosis stage?  If yes, please submit fibrosis stage, date, and method(s) used. | Y | 1004 |
| N | 1235 |
| 5 | 1004 |  | Select | Is the patient scheduled to receive an HCVNS3 protease inhibitor (i.e. grazoprevir, voxilaprevir, glecaprevir)? | Y | 1005 |
| N | 1006 |
| 6 | 1005 |  | Select and Free Text | Has the patient been assessed for a history of decompensated liver disease and liver disease severity using the Child-Turcotte-Pugh (CTP) score if cirrhosis is determined to be likely present (as evidenced by clinical findings, radiology, Metavir fibrosis score of F4, pathology findings or other laboratory markers (FibroTest/FibroSure/FIB-4 index)?  If yes, please provide documentation to support the request. | Y | 1006 |
| N | 1235 |
| 7 | 1006 |  | Select | Has the prescriber discussed the importance of adherence to treatment plan, office visits, lab monitoring, imaging, procedures and to taking requested regimen as prescribed? | Y | 1007 |
| N | 1235 |
| 8 | 1007 |  | Select | Does the patient have a limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions? | Y | 1235 |
| N | 1008 |
| 9 | 1008 |  | Select | Does the patient’s regimen include ribavirin? | Y | 1009 |
| N | 1013 |
| 10 | 1009 |  | Select | Does the patient have ANY of the following:   * CrCl less than 50 mL/min (unless dose is adjusted) * Hypersensitivity to ribavirin * History of severe or unstable cardiac disease * Pregnant women and men with pregnant partners * Diagnosis of hemoglobinopathy (e.g. thalassemia major, sickle cell anemia) * Baseline platelet count less than 70,000 cells/mm3 * ANC less than 1,500 cells/mm3 * Hb less than 12gm/dl in women or less than 13g/dL in men | Y | 1010 |
| N | 1011 |
| 11 | 1010 |  | Free Text | Please indicate which of the following apply to the patient:  1. CrCl less than 50 mL/min (unless dose is adjusted)  2. Hypersensitivity to ribavirin  3. History of severe or unstable cardiac disease  4. Pregnant women and men with pregnant partners  5. Diagnosis of hemoglobinopathy (e.g. thalassemia major, sickle cell anemia)  6. Baseline platelet count less than 70,000 cells/mm3  7. ANC less than 1,500 cells/mm3  8. Hb less than 12gm/dl in women or less than 13g/dL in men | END (Pending Manual Review) | |
| 12 | 1011 |  | Select | Is the patient a woman of childbearing potential or a male patient with a female partner of childbearing potential? | Y | 1012 |
| N | 1013 |
| 13 | 1012 |  | Select | Has the provider confirmed all of the following:   * Patient is not pregnant (or a male with a pregnant female partner) and not planning to become pregnant during treatment or within 6 months of stopping * Agreement that partners will use two forms of effective contraception during treatment and for at least 6 months after stopping * Verification that monthly pregnancy tests will be performed throughout treatment | Y | 1013 |
| N | 1235 |
| 14 | 1013 |  | Select | What is the patient’s treatment status? | Treatment naïve | 1014 |
| Treatment experienced | 2000 |
| Re-infection of Allograft Liver after Transplant | 3000 |
| Decompensated Cirrhosis | 4000 |
| Other | 1235 |
| 15 | 1014 |  | Select | What is the patient’s cirrhosis status? | No cirrhosis | 1015 |
| Compensated cirrhosis | 1016 |
| Other | 1235 |
| 16 | 1015 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Mavyret 100/40 mg, three (3) tablets daily for 8 weeks | 1231 |
| sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks | 1231 |
| Other | 1228 |
| 17 | 1016 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (GT4 WITH HIV coinfection, IDSA/AASLD guidelines recommend 12 weeks of therapy) | 1231 |
| sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive) | 1231 |
| Other | 1228 |
| 18 | 2000 |  | Select | Please select the regimen previously failed: | Sofosbuvir-based regimen | 2001 |
| NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier) | 2002 |
| Mavyret | 2003 |
| Vosevi or sofosbuvir + Mavyret | 2004 |
| GT 3 only: sofosbuvir/NS5A (e.g. Harvoni) | 2005 |
| Other | 1235 |
| 19 | 2001 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Mavyret 100/40 mg, three (3) tablets daily for 16 weeks | 1225 |
| Other | 1225 |
| 20 | 2002 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Vosevi 400/100/100 mg, one tablet daily for 12 weeks | 1225 |
| Other | 1225 |
| 21 | 2003 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Vosevi 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight-based RBV) | 1225 |
| Other | 1225 |
| 22 | 2004 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 24 weeks | 1225 |
| Other | 1225 |
| 23 | 2005 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 12 weeks | 1225 |
| Other | 1225 |
| 24 | 3000 |  | Select | Please select from one of the following: | Direct Acting Antivirals (DAA)-treatment naïve, no decompensated cirrhosis | 3001 |
| Direct Acting Antivirals (DAA)-treatment experienced, no decompensated cirrhosis | 3002 |
| Direct Acting Antivirals (DAA)-treatment experienced, multiple negative baseline characteristics | 3003 |
| Treatment naïve, decompensated cirrhosis | 3004 |
| Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY) | 3005 |
| Other | 1235 |
| 25 | 3001 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Mavyret 100/40 mg, three (3) tablets daily for 12 weeks | 1231 |
| sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks | 1231 |
| Other | 1228 |
| 26 | 3002 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Vosevi 400/100/100 mg, one tablet daily for 12 weeks | 1225 |
| Other | 1225 |
| 27 | 3003 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | Vosevi 400/100/100 mg, one tablet daily + low dose RBV for 12 weeks | 1225 |
| Other | 1225 |
| 28 | 3004 |  | Select | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting. | sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 12 weeks | 1231 |
| Other | 1228 |
| 29 | 3005 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 24 weeks | 1225 |
| Other | 1225 |
| 30 | 4000 |  | Select | Please select the regimen previously used: | No prior sofosbuvir or NS5A failure | 4001 |
| Prior sofosbuvir or NS5A failure | 4002 |
| Other | 1235 |
| 31 | 4001 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV recommended for Child-Pugh class C cirrhosis) | 1231 |
| sofosbuvir/velpatasvir 400/100 mg daily for 24 weeks (will be approved only for patients with documented ineligibility for RBV) | 1231 |
| Other | 1228 |
| 32 | 4002 |  | Select and Free Text | The Ohio Department of Medicaid allows the following treatment regimens. Please select the regimen you are requesting.  If other, please enter drug regimen requested, including drug names, doses, and duration of treatment. | sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C) | 1225 |
| Other | 1225 |
| 33 | 1225 |  | Select and Free Text | Has the provider submitted documentation of the following:  Prior treatment regimens, dates & outcomes, including reason for failure, if known (e.g. failed to complete prior therapy, failure of past therapy)? | Y | 1228 |
| N | 1235 |
| 34 | 1228 |  | Select and Free Text | Has the provider submitted documentation of the patient’s genotype, treatment history, and extent of liver disease?  If yes, please submit documentation. | Y | 1229 |
| N | 1235 |
| 35 | 1229 |  | Select | Is the provider requesting a regimen that is not outlined by the Ohio Department of Medicaid (I.e. If selected “Other” for regimen during previous questions)? | Y | 1230 |
| N | 1231 |
| 36 | 1230 |  | Select and Free Text | Has the provider submitted clinical rationale for selecting regimens other than those outlined by the Ohio Department of Medicaid?  If yes, please submit documentation. | Y | 1231 |
| N | 1235 |
| 37 | 1231 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 1232 |
| N | 1235 |
| 38 | 1232 |  | Select | Is this request being prescribed in accordance with a regimen recommended by the American Association for the Study of Liver Diseases (AASLD)? | Y | 1233 |
| N | 1235 |
| 39 | 1233 |  | Select and Free Text | Is the request for a preferred medication?  Please note, the preferred medications are:   * Mavyret, Pegasys, Ribavirin, Sofosbuvir/Velpatasvir   Please note: Regimens including pegylated Interferons must include close monitoring with periodic clinical and laboratory evaluations. | Y | END (Pending Manual Review) |
| N | 8998 |
| 40 | 8998 |  | Select and Free Text | Has the patient had an inadequate clinical response defined as not achieving SVR with guideline-recommended preferred drugs?  If yes, please submit the medication trials and dates. | Y | 9000 |
| N | 8999 |
| 41 | 8999 |  | Select and Free Text | Has the provider submitted documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances)?  Requests for patients established on current therapy with prior payer (i.e., Commercial, Fee-for-Service, Managed Care Plan, etc) will be authorized with documentation.    If yes, please submit the medication name and reason for inability to use. | Y | 9000 |
| N | 1236 |
| 42 | 9000 |  | Select | Is the request for any of the following:  1) a nonsolid oral dosage formulation  2) a non-preferred extended release formulation  3) a non-preferred brand name that has a preferred generic product | Y | 9001 |
| N | END (Pending Manual Review) |
| 43 | 9001 |  | Select and Free Text | Has the provider submitted documentation of medical necessity for the requested product (i.e. medical reasons for why the patient cannot be changed to a solid oral dosage formulation, inadequate clinical response with a product’s immediate release formulation, or inadequate clinical response or allergy of two or more generic labelers)? | Y | END (Pending Manual Review) |
| N | 1235 |
| 44 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |
| 45 | 1236 |  | Free Text | Please explain the reason(s) why the patient is unable to use medications not requiring prior approval. | END (Pending Manual Review) | |

LENGTH OF AUTHORIZATIONS: Up to the length authorized by the American Association for the Study of Liver Disease (AASLD) guidelines.

|  |  |
| --- | --- |
| **Last Approved** | 10/24/2023 |
| **Other** | INTERNAL NOTE: Please evaluate the patient’s regimen and authorize other applicable agents such as ribavirin (if appropriate). Please notify prescriber accordingly. |