PHARMACY PRIOR AUTHORIZATION INFORMATION
Division of Medicaid
Pharmacy Prior Authorization Unit
550 High St., Suite 1000, Jackson, MS 39201

Additional Instructions for Completing a Medicaid Pharmacy Prior Authorization

***Notice**: DOM encourages Medicaid providers to use equally efficacious and cost saving preferred agents whenever possible; most preferred drugs do not require PA. There are multiple preferred alternatives for non-preferred drugs. Before submitting a PA request, remember to check for options not requiring PA at the current PDL which may be referenced at* http://www.medicaid.ms.gov/providers/pharmacy/pharmacy-prior-authorization/

Completing a Prior Authorization – Main Page

- Please note the instructions on this page are for beneficiaries enrolled in fee-for-service Medicaid. For Medicaid beneficiaries, who obtain prescription drug benefits through MSCAN, or coordinated care plans, refer to https://medicaid.ms.gov/programs/mississippican/mississippican-prior-authorization-information/ for information.
- MS Division of Medicaid requires that all information requested on this form be completed for consideration of approval. The requested information is required by the Pharmacy PA Unit in order to quickly assess the prior authorization request. Requests submitted with missing information will not be assessed until that information is provided.
- Only the prescribing provider or one of their staff representatives can request a pharmacy prior authorization from the Pharmacy Prior Authorization unit.
- PA requests submitted by agents of drug manufacturers will be denied. When a claim returns the NCPDP request code 75 ("Prior Authorization Required"), a prior authorization is needed.

There are two options to request the prior authorization:

A.) Online: ***RECOMMENDED*** *-The quickest, most efficient way to enter and process a Prior Authorization.*

If you are a MS MEDICAID PRESCRIBER, please submit your PA requests via the Change Healthcare provider portal for the most efficient processing. www.msmedicaidrxportal.com

B.) Facsimile: 1-877-537-0720

Prior authorizations are reviewed and a determination notice provided within twenty-four (24) hours from receipt of request. If a PA is not available, a seventy-two (72) hour emergency supply must be dispensed. Pharmacists should use their professional judgment regarding whether or not there is an immediate need every time the seventy-two (72) hour option is used. The seventy-two (72) hour emergency procedure must not be used for routine and continuous overrides.

Emergency Supply

In cases where a prior authorization is medically necessary the Pharmacy PA unit will allow for a 72 hour Emergency http://www.medicaid.ms.gov/providers/pharmacy/pharmacy-resources/ for prior authorized drugs when a PA is not available. The 72-hour emergency procedure should not be used for routine and continuous overrides.

11/03/2016

Prior Authorization Determination

If the Pharmacy PA unit approves the prior authorization, the beneficiary can return to their pharmacy to obtain the prescription. The drug claim will pay and no further action will be required.

If the Pharmacy PA unit denies the request, the prescriber's office will be notified immediately. The prescriber has the option of prescribing a different treatment course that does not require prior authorization or by contacting the Change Healthcare Medicaid Pharmacy PA Unit at 1-877-537-0722 and requesting a first reconsideration.

REMINDER: *Before submitting a PA request, check for options not requiring PA on the current PDL found at http://www.medicaid.ms.gov/providers/pharmacy/preferred-drug-list/ Medicaid providers are encouraged to use equally efficacious and cost saving* ***preferred*** *agents whenever possible.*

Additional Drug Specific Information:

Brand-Name Multi-Source Drug / Dispense As Written (DAW)

The following brand name drugs are excluded from this requirement:

- ***DOM designated narrow therapeutic index drugs or NTI are Coumadin, Dilantin, Lanoxin, Synthroid, and Tegretol.***
- ***Preferred branded drugs on DOM's PDL.***

The completed FDA MedWatch form must be included with this request. *A copy of the FDA MedWatch form may be obtained online at:* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf

Medical Necessity Prior Authorization Form for EPSDT-eligible beneficiaries

The Division of Medicaid has established a program of Early and Periodic Screening., Diagnosis, and Treatment (EPSDT), which provides preventive and comprehensive health services for Medicaid-eligible children and youth up to the age twenty-one (21). The service ends on the last day of the beneficiary's twenty-first (21st) birthday month. See MS Administrative Code, Title 23, Part 223.

Reasons for prior authorization request may include, but are not limited to:
Request for more than 5 prescription claims per month
Request for more than 2 non-preferred/brand name prescription claims per month
Request for a non-preferred drug
Request for a non-covered drug

Early Refill

Rule 1.7: Refills/Renewals of Prescription Drugs

A. A written, faxed, e-prescribed, or telephoned prescription may be refilled, in compliance with the prescriber's order, up to a limit of eleven (11) times per year, if compliant with state and/or federal regulations and guidelines. Additionally, the following are applicable:

1. The absence of an indication to refill by the prescribing provider renders the prescription non-refillable.

2. Refills are reimbursable only if specifically authorized by the prescribing provider.

3. Medicaid does not reimburse for prescription refills that exceed the specific number authorized by the prescribing provider.

4. Medicaid does not reimburse for any refills dispensed after one (1) year from the date of the original prescription.

5. Medicaid does not reimburse for a prescription refill with greater frequency than the approximate interval of time that the dosage regimen of the prescription would indicate, unless extenuating circumstances are documented which would justify the shorter interval of time before the refilling of the prescription.

6. Medicaid does not reimburse for quantities in excess of the prescribing provider's authorization.

B. Medicaid does not reimburse for any refill without an explicit request from a beneficiary or the beneficiary's responsible party, such as a caregiver, for each filling event. The possession, by a provider, of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription.

C. Medicaid beneficiaries or providers cannot waive the explicit refill request and enroll beneficiaries in an electronic automatic refill in pharmacies.

D. Medicaid does not reimburse for a prescription refill until seventy five percent (75%) of the day's supply of the drug has elapsed as indicated on the prescription.

1. For any controlled substance (Schedule III, IV, and V), Medicaid does not reimburse for a prescription refill until eighty five percent (85%) of the day's supply of the drug has elapsed as indicated on the prescription. Any attempt to refill a prescription through the Point-of-Sale system before the twenty-sixth (26th) day will be automatically denied.

2. By law, Schedule II narcotics cannot be refilled.

E. As long as the monthly service limits have not been exhausted, Medicaid may permit an early refill of an original claim under one (1) of the following circumstances:

1. The client's life is at risk,

2. When an acute clinical condition is occurring, which would require extra medication to stop or mitigate further morbidity, or

3. The prescribing provider either increases the dosing frequency or increases the number of tablets per dose. The prescribing provider must document the change in dosage or frequency by writing or phoning in a new prescription. The prescriber(s) who wrote the original prescription must initiate any request for additional medication.

F. Medicaid does not generally reimburse for replacement of prescriptions that are lost, stolen or otherwise destroyed.

1. Replacement of prescriptions is the beneficiary's responsibility.

2. If a beneficiary requires an early refill, the prescribing provider must request an exception override of this requirement by seeking approval from Medicaid's Pharmacy Bureau Prior Authorization (PA) Unit.

Source: Miss. Code Ann. § 43-13-121

Enteral Nutrition

Enteral nutrition is used as a nutritional replacement for patients who are unable to get enough nutrients in their diet. These formulas are taken by mouth or through a feeding tube and are used by the body for energy and to form substances needed for normal body functions. Documentation to support coverage of enteral nutrition must be maintained in the beneficiary's medical record.

A copy of the original prescription or order must accompany this PA request.

• Enteral nutritional replacement products are included in the facilities' per diem rate for residents in a long-term care facility (defined as nursing home, intermediate care facility for individuals with intellectual disabilities [ICF/IID] or psychiatric residential treatment facility [PRTF]). Enteral products ARE NOT REIMBURSABLE separately as a pharmacy "point of sale" service.
• If the beneficiary is Medicare eligible, then Medicare Part B or Medicare Advantage must be billed first as primary coverage.

DOM covers enteral nutrition when the following criteria are met:

1. For beneficiaries with inborn errors of metabolism.

2. For beneficiaries age 21 years or older, the requested enteral nutritional product must be the sole source of nutrition or when there are special circumstances (such as chemotherapy and/or radiation therapy to the head and neck region, etc.) that justify the need for enteral nutrition.

3. For EPSDT-eligible beneficiaries, specialized enteral feedings must constitute more than 50% of the nutritional needs. A qualifying diagnosis is required.

- EPSTD beneficiaries up to age 5 years must be registered with the federal program for women, infants, and children (WIC) in order to receive WIC monthly nutritionals. If WIC eligible, DOM *may* allow up to a 30 day transition period for NEW starts on WIC covered products.
- Provide an estimate of initial coverage needs until WIC benefits start or if there is a gap in coverage of WIC benefits (up to, but not more than, a 30-day supply).
- Please attach and FAX to 877-537-0720 a copy of the WIC program formula request form when submitting this PA form. Include the WIC Monthly Quantity Limit and the average amount needed after WIC benefits are exhausted.

4. The unique composition of the formula must contain nutrients the beneficiary is unable to obtain from food. The composition of the formula must represent an integral part of the treatment of the specified diagnosis and/or condition.

It must be documented that the beneficiary is either unable to take oral nutrition or unable to sufficiently maintain life without an enteral nutritional replacement product.

Approval may be granted for up to 12 months. A prior authorization for enteral nutrition is for the nutritional product only and *does not* include supplies necessary to administer the nutrient.

MAXIMUM UNIT OVERRIDE

- In accordance with state law, Medicaid provides up to a 31-day supply of medications.
- The maximum daily dose is determined according to the FDA-approved and manufacturer's suggested recommended daily dose.
- Some drugs have assigned monthly quantity limits, as recommended by DOM's Drug Utilization Review Board, and are subject to the Maximum Unit Override. The specific agents with the corresponding quantity limits can be found at http://www.medicaid.ms.gov/providers/pharmacy/pharmacy-resources/
- Medicaid may request chart documentation for verification of submitted information.

Criteria for Maximum Unit Override: The request for doses higher than the maximum quantity allowed by Medicaid must be submitted for prior approval:
• The request must be substantiated by diagnosis and supporting medical justification.
• Supporting documentation must be available in the patient record.
• Medication will not be approved for non-FDA approved indications.

Preferred Drug List Exception Request

Rule 1.10: Preferred Drug List

A. The Division of Medicaid recommends that prescribers use the drugs on the Preferred Drug List (PDL).

1. The PDL is defined as a list of drugs reviewed and proposed by the Pharmacy and Therapeutics (P&T) Committee, comprised of a group of prescribers, pharmacists, nurse practitioners, and/or other health care professionals. Final approval of the PDL is the responsibility of the Executive Director of the Division of Medicaid.

2. The PDL contains a wide range of generic and preferred brand name products approved by the FDA.

3. A medication becomes a preferred drug based first on safety and efficacy, then on cost-effectiveness.

B. Prior authorizations for non-preferred drugs may be approved for medically accepted indications when criteria have been met.

C. Drugs must be prescribed and dispensed in accordance with medically accepted indications for uses and dosages. No payment will be made under the Medicaid program for services, procedures, supplies or drugs still in clinical trials and/or investigative or experimental in nature.

D. The PDL is subject to change. Refer to the Division of Medicaid's website for a current listing of prescription drugs on the PDL.

Source: Miss. Code Ann § 43-13-121; Section 127 Social Security Act

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Hepatitis C Therapy PA Request
Guidelines for Regimen Selection and Definitions

The Mississippi Division of Medicaid (DOM) will approve Hepatitis C treatment PA requests for members who meet the following criteria:

- Requested regimen is compliant with latest American Association for The Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (ISDA) Recommendations for Testing, Managing, and Treating Hepatitis C *(* http://www.hcvguidelines.org/full-report-view)
  AND
  The regimens listed under each genotype and clinical scenario below are the preferred regimens for MS Medicaid beneficiaries, based on clinical and cost considerations and are consistent with AASLD/IDSA guidelines.
- **OR**
  Clinical rationale is provided for using a regimen that is beyond those within the current guidelines, or for selecting regimens using non-preferred drugs on the Mississippi Division of Medicaid Universal Preferred Drug List

On the PA Request Form, which must be approved prior to the 1st dose, document the clinical condition supporting the requested regimen. Unless otherwise specified, you do not need to attach documentation to the form. You are attesting to the fact that documentation is available in the patient chart for all information you provide.

DEFINITIONS USED ON PA FORM:

Ribavirin-Ineligible (documentation exists in the patient's chart for at least one of the following):

- Hypersensitivity to RBV
- 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 < 70,000 cells/mm3
- ANC < 1500 cells/mm3
- Hb < 12 gm/ml in women or <13 g/dl in men

RENAL DYSFUNCTION

Patients with CrCl <50 ml/mm should not be treated with ribavirin.
Patients with CrCl <30 ml/min should not be treated with sofosbuvir containing regimens (including Harvoni/Epclusa).

Preferred Direct Acting Antivirals

Harvoni (ledipasvir/sofosbuvir) 90/400 mg
Sovaldi (sofosbuvir) 400 mg
Technivie (ombitasvir/paritaprevir, ritonavir) 12.5/75/50 mg
Viekira Pak (ombitasvir/paritaprevir/ritonavir) 12.5/75/50mg + (dasabuvir) 250mg
Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir) 200/8.33/50/33.33 mg
Zepatier (elbasvir/grazoprevir) 50/100 mg
Epclusa (sofosbuvir/velpatasvir) 400/100 mg

Non-Preferred Direct Acting Antivirals

Daklinza (daclatasvir) 60 mg
Olysio (simeprevir) 150 mg

Preferred Regimens Listed Below

SUBMISSION AND/OR APPROVAL OF A DRUG PRIOR AUTHORIZATION REQUEST DOES NOT GUARANTEE MEDICAID PAYMENT FOR PHARMACY PRODUCTS OR THE AMOUNT OF PAYMENT. ELIGIBILITY FOR AND PAYMENT OF MEDICAID SERVICES ARE SUBJECT TO ALL TERMS AND CONDITIONS AND LIMITATIONS OF THE MEDICAID PROGRAM.

Genotype 1 (Note the subtype is only indicated when treatment is different for subtypes)

Treatment naïve, no cirrhosis

- ☐ 1a/1b Harvoni - one tablet daily for 8 weeks (viral load < 6 million copies AND HIV negative only)
- ☐ 1a/1b Harvoni- one tablet daily for 12 weeks
- ☐ 1a: Viekira Pak- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) plus weight-based RBV for 12 weeks
- ☐ 1b: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) for 12 weeks
- ☐ 1a: Zepatier- one tablet daily for 12 weeks in patients without baseline NS5A polymorphisms
- ☐ 1b: Zepatier- one tablet daily for 12 weeks

Treatment naïve, compensated cirrhosis

- ☐ Harvoni- one tablet daily for 12 weeks
- ☐ 1a: Viekira Pak- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)-two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) plus weight-based RBV for 24 weeks (Child-Pugh (CP) Class A ONLY, contraindicated for CP-B or CP-C)
- ☐ 1b: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) for 12 weeks (CP-A ONLY, contraindicated for CP-B or CP-C)
- ☐ 1a: Zepatier- one tablet daily for 12 weeks in patients without baseline NS5A polymorphisms
- ☐ 1b: Zepatier- one tablet daily for 12 weeks

Treatment experienced, no cirrhosis (drugs that patient has had experience with listed in parentheses)

- ☐ Harvoni- one tablet daily for 12 weeks (PEG-IFN/RBV OR PEG-IFN/RBV + PI)
- ☐ 1a: Viekira Pak- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg)-BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) plus weight-based ribavirin for 12 weeks (PEG-IFN/RBV)
- ☐ 1b: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) for 12 weeks (PEG-IFN/RBV)
- ☐ Harvoni- one tablet daily plus weight-based RBV for 12 weeks (Sovaldi plus ribavirin WITH or WITHOUT PEG-IFN)

Note: If prior treatment with NS5A such as daclatasvir with sofosbuvir, ledipasvir/sofosbuvir or ombitasvir, paritaprevir, ritonavir and dasabuvir or simeprevir with sofosbuvir), recommendation is to defer treatment pending more data

- ☐ 1a: Zepatier- one tablet daily for 12 weeks (PEG-IFN+RBV) in patients without baseline NS5A polymorphisms
- ☐ 1a: Zepatier- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN + RBV + HCV NS3/4A PI: boceprevir, simeprevir, or telaprevir) in patients without baseline NS5A polymorphisms
- ☐ 1b: Zepatier- one tablet daily for 12 weeks (PEG-IFN+RBV)
- ☐ 1b: Zepatier- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN + RBV + HCV NS3/4A PI: boceprevir, simeprevir, or telaprevir)

Continued-–Genotype 1 (Note the subtype is only indicated when treatment is different for subtypes)

Treatment experienced, cirrhosis (drugs that patient has had experience with listed in parentheses)

- ☐ Harvoni- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN/RBV OR PEG-IFN/RBV+PI – NOT FOR Olysio/Sovaldi experienced)
- ☐ Harvoni- one tablet daily for 24 weeks (PEG-IFN/RBV OR PEG-IFN/RBV+PI ONLY if documented ineligible for RBV)
- ☐ Harvoni- one tablet daily + weight based RBV for 24 weeks (Sovaldi/RBV +/-PEG-IFN)
- ☐ 1a: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets AM and dasabuvir (250 mg)- BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) plus weight-based RBV for 24 weeks (PEG-IFN/RBV) (CP-A ONLY, contraindicated for CP-B or CP-C)
- ☐ 1b: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) for 12 weeks (PEG-IFN/RBV) (CP-A ONLY, contraindicated for CP-B or CP-C)

Note: If prior treatment with daclatasvir with sofosbuvir, ledipasvir/sofosbuvir, simeprevir/sofosbuvir or ombitasvir, paritaprevir, ritonavir and dasabuvir and in urgent need of treatment, recommendation is to test for resistance associated variants and treat with RBV containing regimen for 24 weeks.

- ☐ 1a: Zepatier- one tablet daily for 12 weeks (PEG-IFN+RBV) in patients without baseline NS5A polymorphisms
- ☐ 1a: Zepatier- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN + RBV + HCV NS3/4A PI: boceprevir, simeprevir, or telaprevir) in patients without baseline NS5A polymorphisms
- ☐ 1b: Zepatier- one tablet daily for 12 weeks (PEG-IFN+RBV)
- ☐ 1b: Zepatier- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN + RBV + HCV NS3/4A PI: boceprevir, simeprevir, or telaprevir)

Genotype 2

Treatment naïve, no cirrhosis

- ☐ Epclusa-one tablet daily for 12 weeks

Treatment naïve, compensated cirrhosis

- ☐ Epclusa-one tablet daily for 12 weeks

Treatment experienced (PEG-IFN + ribavirin), with or without cirrhosis

- ☐ Epclusa-one tablet daily for 12 weeks

Treatment experienced (sofosbuvir + ribavirin)

- ☐ Epclusa-one tablet daily + weight-based ribavirin for 12 weeks
- ☐ Daklinza-one tablet daily + Sovaldi-one tablet daily for 24 weeks (ONLY if RBV ineligible: document on PA form)

Decompensated cirrhosis

- ☐ Epclusa-one tablet daily + weight-based ribavirin for 12 weeks

Re-infection of allograft liver after transplant, no or compensated cirrhosis

- ☐ Daklinza- one tablet daily plus Sovaldi- one tablet daily + low dose RBV for 12 weeks
- ☐ Daklinza- one tablet daily plus Sovaldi- one tablet daily for 24 weeks (ONLY if RBV ineligible – document on PA form)

Re-infection of allograft liver after transplant, decompensated cirrhosis

- ☐ Sovaldi-one tablet daily + low initial dose RBV for 24 weeks

Genotype 3

Treatment naïve, with or without cirrhosis
- ☐ Epclusa-one tablet daily 12 weeks

Treatment experienced (PEG-IFN + ribavirin), no cirrhosis
- ☐ Epclusa- one tablet daily for 12 weeks

Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis
- ☐ Epclusa-one tablet daily plus weight-based RBV for 12 weeks

Treatment experienced (sofosbuvir + ribavirin), no or compensated cirrhosis
- ☐ Epclusa-one tablet daily plus weight-based RBV for 12 weeks

Decompensated cirrhosis
- ☐ Epclusa-one tablet daily + weight-based ribavirin for 12 weeks

Re-infection of allograft liver after transplant, no or compensated cirrhosis
- ☐ Daklinza-one tablet daily plus Sovaldi- one tablet daily + low dose RBV for 12 weeks
- ☐ Daklinza-one tablet daily plus Sovaldi- one tablet daily for 24 weeks (ONLY if RBV ineligible – document on PA form)

Genotype 4

Treatment naïve, no cirrhosis
- ☐ Harvoni-one tablet daily for 12 weeks
- ☐ Technivie- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM, plus weight-based RBV for 12 weeks
- ☐ Zepatier- one tablet daily for 12 weeks

Treatment naïve, compensated cirrhosis
- ☐ Harvoni- one tablet daily for 12 weeks
- ☐ Technivie- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM, plus weight-based RBV for 12 weeks
- ☐ Zepatier -one tablet daily for 12 weeks

Treatment experienced (PEG-IFN + ribavirin), no cirrhosis
- ☐ Harvoni- one tablet daily for 12 weeks
- ☐ Technivie- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM, plus weight-based RBV for 12 weeks
- ☐ Zepatier -one tablet daily for 12 weeks (virologic relapse after PEG-IFN + RBV)
- ☐ Zepatier -one tablet daily plus weight-based RBV for 16 weeks (PEG-IFN+RBV on treatment virologic failure (failure to suppress or breakthrough)

Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis
- ☐ Harvoni one tablet daily + weight-based ribavirin for 12 weeks
- ☐ Technivie- two tablets q AM, plus weight-based RBV for 12 weeks
- ☐ Zepatier- one tablet daily for 12 weeks (virologic relapse after PEG-IFN + RBV)
- ☐ Zepatier- one tablet daily plus weight-based RBV for 16 weeks [(PEG-IFN + RBV on treatment virologic failure (failure to suppress or breakthrough)]

Decompensated cirrhosis
- ☐ Harvoni - one tablet daily + low initial dose ribavirin for 12 weeks
- ☐ Harvoni - one tablet daily for 24 weeks (ONLY if RBV ineligible – document on PA form)
- ☐ Harvoni – one tablet daily plus low initial dose ribavirin for 24 weeks (prior treatment with sofosbuvir only)

Genotype 5 and 6
Regardless of prior treatment or cirrhosis ☐ Harvoni - one tablet for 12 weeks (PEG-IFN/RBV failure)
Other treatment regimen
Genotype _____ Treatment history, and extent of liver disease: _____ _____ _____ Drug name, dose and duration: _____ _____ Clinical rationale for selecting regimens other than those outlined above: _____ _____ _____
Abbreviations: ***PEG-IFN*** *= peginterferon;* ***RBV*** *= ribavirin;* ***PI*** *= protease inhibitor*

For unique patient populations with decompensated cirrhosis, post-liver transplant, renal impairment, or HIV: please refer to the current AASLD Guidelines for recommended treatments. http://www.hcvguidelines.org/full-report-view

If HIV positive: Please refer to the current AASLD Guidelines for potential drug interactions and recommended dosing adjustments.

DRUG INTERACTIONS

Reference: http://hep-druginteractions.org/ provides clinically useful, reliable, current, evidence-based information on relevant drug interactions with hepatitis medications.

Request for an Appeal

Purpose:
In accordance with Section 43-13-116 of the Mississippi Code of 1972, as amended, and 42 CFR 431.200 et. seq., the Division of Medicaid provides beneficiaries the opportunity to request a fair hearing in order to appeal decisions of denial, termination, suspension or reduction of Medicaid covered services.

Policy:
If a decision is made to reduce, deny, suspend or terminate covered services provided to a Medicaid beneficiary, and the beneficiary disagrees with the decision, the beneficiary and/or his/her legal representative must request a hearing in writing within thirty (30) days of the notice of adverse action. Please refer to Miss. Admin. Code Part 100, Chapter 1, Rule 1.3.

Requests should be forwarded to:

Division of Medicaid (DOM)
Attn. Office of Appeals
550 High Street, Suite 1000
Jackson, MS 39201

In an emergency situation, the DOM will allow for a 72 hour supply of medication.

Familial Hypercholesterolemia: REPATHA™ (evolocumab) and PRALUENT® (alirocumab)

Appendix A: Statin Contraindications

- Decompensated liver disease (symptoms can include jaundice, pruritus, ascites, variceal hemorrhage, or hepatic encephalopathy).
- Immune-mediated hypersensitivity to the HMG-CoA reductase inhibitor drug class (statins) as evidenced by an allergic reaction occurring with at least TWO different statins
- Laboratory-confirmed acute liver injury resulting from statin treatment
- Laboratory-confirmed rhabdomyolysis resulting from statin treatment
- Women who are breastfeeding, pregnant or are actively trying to become pregnant

Appendix B: Zetia Contraindications/Reasons to Discontinue

- Moderate or severe hepatic impairment (CP classes B and C)
- Women who are breastfeeding/pregnant or are actively trying to become pregnant
- Immune-mediated hypersensitivity to the cholesterol absorption as evidenced by an allergic reaction including anaphylaxis, angioedema, rash, or urticaria

Appendix C: A moderate-intensity statin may be more appropriate for the following adult populations if not able to tolerate a high-intensity statin

- Multiple or serious comorbidities, including impaired renal or hepatic function
- Unexplained ALT elevations >3 times ULN
- Active liver disease
- History of previous statin intolerance or statin-related muscle disorder
- Patient characteristics or concomitant use of drugs affecting statin metabolism
- ≥75 years of age
- History of hemorrhagic stroke
- Asian ancestry

Clinical atherosclerotic cardiovascular disease (ASCVD) includes:

- Acute coronary syndromes, or history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin.

TABLE 1: Dosage Levels for Statin Therapy Intensity Levels		
Low-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	High-Intensity Statin Therapy
Daily dose lowers LDL-C by < 30%, on average	Daily dose lowers LDL-C by 30% to 50%, on average	Daily dose lowers LDL-C by ≥ 50%, on average
• Simvastatin 10 mg • Pravastatin 10-20 mg • Lovastatin 20 mg • Fluvastatin 20-40 mg • Pitavastatin (Livalo) 1 mg	• Atorvastatin 10-20 mg • Rosuvastatin 5-10 mg • Simvastatin 20-40 mg • Pravastatin 40-80 mg • Lovastatin 40 mg • Fluvastatin XL (Lescol XL) 80 mg • Fluvastatin 40 mg twice daily • Pitavastatin (Livalo) 2-4 mg	• Atorvastatin 40-80 mg • Rosuvastatin 20-40 mg

TABLE 2: Dutch Lipid Clinic Network criteria for Familial Hypercholesterolemia	
Criteria	**Points**
Family History	
First-degree relative with known premature* coronary and vascular disease, **OR** First-degree relative with known LDL-C level above the 95th percentile	1
First-degree relative with tendinous xanthomata and/or arcus cornealis, **OR** Children aged < 18 years with LDL-C level above the 95th percentile	2
Clinical History	
Patient with premature* coronary artery disease	2
Patient with premature* cerebral or peripheral vascular disease	1
Physical examination	
Tendinous xanthomata	6
Arcus cornealis prior to age 45 years	4
Cholesterol levels mg/dL (mmol/liter)	
LDL-C ≥330 mg/dL (≥8.5)	8
LDL-C 250 – 329 mg/dL (6.5 – 8.4)	5
LDL-C 190 – 249 mg/dL (5.0 – 6.4)	3
LDL-C 155 – 189 mg/dL (4.0 – 4.9)	1
DNA analysis	
Functional mutation in the *LDLR, apo B* or *PCSK9* gene	8
Diagnosis (diagnosis is based on total number of points obtained)	
Definite familial hypercholesterolemia	>8
Probable familial hypercholesterolemia	6 – 8
Possible familial hypercholesterolemia	3 – 5
Unlikely familial hypercholesterolemia	<3

*Premature – men < 55 years or women < 60 years Apo B= apoliprotein B
LDL-C= low density lipoprotein cholesterol; LDLR=low density lipoprotein receptor FH=familial hypercholesterolemia
PCSK9=Proprotein convertase subtilisin/kexin type 9