Direct Acting Antiviral (DAA) Drug Access Protocol

TABLE OF CONTENTS

ACRONYMS

ADAP	AIDS Drug Assistance Program
CPA	Clinical Prior Authorization
DAA	Direct-acting Antiviral
NPPA	Non-preferred Prior Authorization
PA	Prior Authorization
PAP	Patient Assistance Program
SPAP	State Pharmacy Assistance Program
TIAP	Texas Insurance Assistance Program

GENERAL INFORMATION

o WHAT IS DIRECT ACTING ANTIVIRAL (DAA's)?

Direct-acting antivirals (DAA's) are a relatively new class of medication used to treat Hepatitis C (HCV) they target specific steps in the HCV viral life cycle. The goals of DAA's are to shorten the length of therapy, minimize side effects, target the virus itself, and improve sustained virologic response (SVR) rate.

o WHAT IS A PATIENT ASSISTANCE PROGRAM (PAP)?

A patient assistance program (PAP) is a program run through pharmaceutical companies to provide free or low- cost medications to people with low incomes who do not qualify for any other insurance programs, such as Medicaid, Medicare or AIDS Drug Assistance Programs also known as Texas HIV Medication Program (ADAP/ THMP). Each individual company has different eligibility criteria for application and enrollment in their patient assistance program.

o WHAT IS AIDS Drug Assistance Program (ADAP) and Texas HIV Medication Program (THMP)?

The AIDS Drug Assistance Program (ADAP) is a state program that provides HIV- related medications to low-income people living with HIV/AIDS who have limited or no health coverage from private insurance, Medicaid, or Medicare.
The Texas HIV Medication Program (THMP) is the official AIDS Drug Assistance Program (ADAP) for the State of Texas.
The Texas HIV Medication Program (THMP) is the official AIDS Drug Assistance Program (ADAP) for the State of Texas.

o ACCESSING DAA's FOR HIV/HCV CO -NFECTION

o UNINSURED PATIENTS

- HIV/HCV co-infected patients can access DAA's through ADAP if they meet the eligibility criteria.
- If they do not qualify for ADAP they might be able to get their medication using PAP's offered through various pharmaceutical companies.

o INSURED PATIENTS

- MEDICAID
  - Apply to Medicaid for DAA's.
  - If rejected by Medicaid then apply to ADAP HCV pilot program to access DAA's.
  - Add Medicaid rejection letter to ADAP application.
  - ADAP is a payer of last resort.
- MEDICARE
  - Patient must have Medicare Part D insurance.
  - Follow the drug formulary criteria per each part D company.
  - Copay assistance available through various companies. (see Medicare section)
- PRIVATE INSURANCE
  - Follow criteria from each insurance company.
  - Apply for copay assistance from the various pharmaceutical companies.
  - Utilize copay/discount cards to reduce patient cost.

ACCESSING DAA's THROUGH PATIENT ASSISTANCE PROGAMS (PAP's)

DAKLINZA (daclatasir) – Bristol-Meyers Squibb

Bristol-Meyers Squibb has the Patient Assistance Foundation and the Patient Support Connect Copay Program to provide medication assistance to both insured and uninsured patient who qualify for Daklinza.

o Patient Support Connect co-pay Program (insured patients)

The Patient Support Connect program will cover the out-of-pocket costs for Daklinza (daclatasvir) for up to a maximum benefit of $5,000 per 28-day supply of 30 mg or 60 mg OR up to a maximum benefit of $10,000 per 28-day supply of 90 mg.

o Eligibility Criteria

You may be eligible for the Co-Pay Program if:

- You are insured by commercial insurance and your insurance coverage does not cover the full cost of your prescription, that is, you have a Co-Pay obligation;
- You do not have prescription insurance coverage through a state or federal healthcare program, including but not limited to Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA) or Department of Defense (DOD) programs; patients who move from commercial to a state or federal healthcare program will no longer be eligible
- You are 18 years of age or older; and
- You are a resident of the United States or Puerto Rico

o Link

Apply for co-pay card directly using this link:
https://bmsdm.secure.force.com/patientsupportconnect/patient

o Bristol- Myers Squibb Patient Assistance Foundation (BMSPAF) (uninsured patients)

o Eligibility Criteria

If you have been prescribed Daklinza you may be eligible for the BMSPAF if you:

- Do not have insurance coverage for your medicine listed on this site.
- Live in the United States, Puerto Rico or US Virgin Islands.
- Are treated by a US licensed prescriber.
- Are being treated as an outpatient.
- Have a yearly income that is at or below 300% Federal Poverty Level (FPL), $35,640 for a single person or $48,060 for a family size of two. Larger family sizes are adjusted accordingly.
- Patients who have Medicare Part D plan must spend at least 3% of your yearly household income on out-of-pocket prescription expenses that calendar year.

o Required documentation.

- Acceptable documentation for Proof of income:
  - Federal Tax Return (1099, 1040 ez)
  - W2
  - Social security Benefits
  - Bank Statements
- Medicare Part D recipients: If you have spent 3% of your annual income on out of pocket prescription costs, please contact your pharmacy to provide you with a report to document your yearly out of pocket expenses. Report must be attached to the application.

o Link

Use this link to access the enrollment form. All required fields MUST be completed and signed.
http://www.bmspaf.org/Documents/BMSPAF-Enrollment-Form.pdf

EPCLUSA (sofosbuvir/velpstasvir), HARVONI (ledipasvir/sofobuvir), SOVALDI (sofosbuvir), VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)- GILEAD

Gilead Support Path Program provides medication assistance for both insured and uninsured patients who qualify. Use the link provided below to access copay cards and enrollment form for uninsured patients.

o Support Path Program co-pay assistance (Insured patients)

- The co-pay cards are only valid for 6 months after activation.
- A prescription claim should be run before copay card is activated.

o Eligibility Criteria

- Must have insurance.
- Not valid for patients enrolled in government healthcare prescription drug programs, such as Medicare Part D and Medicaid. Patients in the coverage gap known as the "donut hole" also are not eligible.

o Support Path Program (Uninsured patients)

Access the enrollment form using the link below.

o Required documentation.

- **Acceptable documentation for Proof of income:**
  - **Federal** Tax Return (1099, 1040 ez)
  - W2 form (2 most recent paystubs within 90 days)
  - Social Security Benefits: most recent year award letter.
  - Bank Statements- direct deposit for social security, SSDI, VA benefits.

o Gilead Support Path Program provides assistance with:

- Benefit investigation: they will assist with insurance verification, get copay amount, deductibles (out of pocket amount the patient have to pay) from the patient's insurance if the insurance card is not available.
- Prior authorization (P/A) and Appeals Information: Provides information to the doctor if the insurance company requires the doctor to complete a Prior Authorization for Gilead medication. Provides follow up with health insurers regarding the status of the Prior Authorization request and get updates on information needed.

o Link

Use this link to access co-pay assistance (insured patients with copay's) and patient assistance (uninsured patients).
http://www.mysupportpath.com/

MAVYRET(glecaprevir/pibrentasvir),TECHNIVIE (ombitasvir/paritaprevir/ritonavir), VIEKERA XR (dasbuvir/ombitasir/paritaprevir/ritonavir extended-release), VIEKERA PAK (ombitasvir,paritaprevir, ritonavir and dasabuvir) – ABBVIE.

ABBVIE has the Patient Assistance Application program, which provides MAVYRET, TECHNIVIE, VIEKIRA XR and VIEKIRA PAK at no cost to eligible uninsured and underinsured patients experiencing financial difficulty. Insured patients with commercial insurance may get co-pay assistance using he copay-savings card. (Link provided below)

o ABBVIE PATIENT ASSISTANCE APPLICATION PROGRAM (Uninsured patients)

- Call **855-765-0504** and request an enrollment form for all the HCV medications by ABBIVE.

o Eligibility criteria

- Proof of income: this includes all member of the household.
- Acceptable documents for proof of income.
    - A copy of the patient's current federal tax return is preferred.
    - 2 pay stubs within the year of the application.
    - A notarized letter of proof of support is acceptable proof of income if the patient is unemployed.

****To prevent processing delays, complete all sections of the enrollment form, sign and date before faxing.**

****** **Approval may take 2 to 3 months based on the medication.**

o Eligibility Requirements for ABBVIE copay assistance (Insured patients)

- Available to patients with commercial prescription insurance coverage.
- Co-pay assistance program is not available to patients receiving prescription reimbursement under any federal, state or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, and Department of Defense or Veteran's Affairs programs). If at any time a patient begins receiving prescription drug coverage under any such federal, state or government-funded healthcare program, patient will no longer be able to use the AbbVie HCV Co-pay Card and the patient must call PSKW at 1-844-865-8725 to stop participation.

o Link

Co-pay card for Technivie, Viekira Xr, Viekira Pak- insured patients.
https://www.viekira.com/patient-support/financial-resources

Co-pay savings card for Mavyret- insured patients.
https://www.mavyret.com/copay-savings-card. Technical support for ABBVIE copay card: 800-422-5604

ZEPATIER (grazoprevir/elbasvir) – MERCK

Merck provides assistance through the Merck Patient Assistance Program.

o Merck Patient Assistance Program (private/commercial insurance only)

- The coupon is valid for up to 28 tablets per prescription and 112 tablets in total.
- Savings are limited to the amount of patient's out-of-pocket cost over $5 per qualifying prescription, up to a maximum benefit of 25% of the catalog price of ZEPATIER (as set by the manufacturer at the time of purchase) per prescription. Coupon savings may not exceed the patient's actual out-of-pocket cost.

Eligibility Criteria

- Must have insurance.
- This is not valid for uninsured patients or patients covered under Medicaid (including Medicaid patients enrolled in a qualified health plan purchased through a health insurance exchange [marketplace] established by a state government or the federal government), Medicare, a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered), TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan ("Healthcare Reform"), or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program (collectively, "Government Programs").
- You must be 18 years of age or older to redeem the coupon.
- The coupon can be used only by eligible residents of the United States or the Commonwealth of Puerto Rico at participating eligible retail or mail-order pharmacies in the United States or the Commonwealth of Puerto Rico.

o Link

Apply for co-pay card using this link:
https://www.activatethecard.com/7582/#

ACCESSING DAA's THROUGH ADAP/THMP

All eligible patients must first be enrolled on the ADAP/THMP, then enroll in the HCV pilot program through THMP. The eligibility criteria and link to enrollment forms for both ADAP/TMPH and HCV pilot program are below.

o Eligibility Criteria:

Any Texas resident who:

- Has a diagnosis of HIV disease and meets the drug-specific eligibility criteria of one or more of the drugs listed above and;
- Is under the care of a Texas-licensed physician who prescribes the medication(s) and;
- Meets the financial eligibility criteria of the program.
- A person is financially eligible if he or she is not presently covered for the medication(s) under the Texas Medicaid Program, or has utilized their Medicaid pharmacy benefits for the month and; is not covered for the medication(s) by any other third-party payer and; has an adjusted gross income, when combined with the gross income of his/her spouse, that does not exceed 200 percent of the current Federal poverty income guidelines (as shown below). The THMP will determine if the person satisfies this criterion from information provided by the person on the Program application.

o Link to ADAP Application:

THMP Application

o THMP HCV PILOT PROGRAM

When the patient is approved for ADAP, the physician must complete the Medical Certification form, to request any and all medications currently available on the Hep. C pilot program through THMP.

o Eligibility Criteria:

- Age 18 or older
- Co-infected with chronic HCV genotype 1, 2, 3, 4 or 5 and HIV, with a certification from their medical provider indicating the client is a good candidate for HCV treatment
- Negative pregnancy test, if applicable
- Prescriber must be experienced in HCV care or treating in collaboration with a specialist in HCV care, agree to monitor patient during the treatment, and maintain an appropriate treatment plan
- Income-eligible for participation in the ADAP (income at or less than 200 percent of federal poverty level)

o INCOME GUIDELINES (based on 200% of Federal Poverty Income Guidelines for 2018)

Family unit size	Income may not exceed
1	$24,280
2	$32,920
3	$41,560
4	$50,200
5	$58,840
>5	$ 8,640 for each additional person

- Actively filling HIV medication prescriptions
- Review for other funding sources including Medicare, Medicaid, VA, Private Insurance, and Pharmaceutical Company Patient Assistance Programs (PAP)
- The client's medical provider is willing to share follow-up data and documentation on the enrolled patient at 12-week intervals

Eligibility will be denied or the client will be dis-enrolled for the following reasons:

- Patient has previously failed to complete therapy with DAA for HCV due to patient non-adherence to therapy due to substance abuse and required enrollment in treatment program has failed.
- Patient is non-adherent to therapy for more than 7 days
- Insufficient resources to procure DAA.
- Exceptions will be considered for circumstances beyond the prescriber or patient's control.

o Link to Medical Certification form for Hep.C pilot program:

Hepatitis C Medical Certification Form

OTHER ASSISTANCE PROGRAMS UNDER THE UMBRELLA OF THE ADAP PROGRAM

o SPAP (State Pharmacy Assistance Program)

- Developed to assist eligible clients with Medicare following the creation of the prescription drug benefit Medicare Part D in 2006.
- Provides assistance with Medicare Part D out of pocket costs.
- The patient must be enrolled in a Medicare Part D plan or a Medicare Advantage Plan with drug coverage to participate in this program.
- Same eligibility criteria as ADAP.

o TIAP (Texas Insurance Assistance Program)

- Developed to assist patients who lost insurance coverage to transition to COBRA and to help patients with unaffordable medication copays.
- Patients must be eligible for COBRA or have a current insurance plan for program participation.
- Same eligibility criteria as ADAP and SPAP

ACCESSING DAA's THROUGH MEDICARE

Medicare patients may be eligible for copay assistance for HCV medications through various independent co-pay foundations.

o INDEPENTENT CO-PAY FOUNDATIONS

o The Patient Advocate Foundation (PAF) Co-Pay Relief Program (CPR)

PAF Co-pay Relief (CPR) provides direct financial assistance to qualified patients, assisting them with prescription drug copayment related to diagnosis.

Maximum award level: $25,000 per year for HCV medications.

o Eligibility Criteria:

- Patient should be insured and insurance must cover the medication for which patient seeks assistance.
- Patient must have a confirmed diagnosis of Hepatitis C.
- Patient must reside and receive treatment in the United States.
- Patient's income must fall below 400% of the Federal Poverty Guideline (FPG) with consideration of the Cost of living index and the number of people in the household.

o CONTACT INFORMATION

Patient Advocate Foundation
Co-Pay Relief Foundation
421 Butler Farm Road
Hampton, Virginia 23666

Toll free: 866-512-3861
Local: 757-952-0118
Fax: 757-952-0119

PAN FOUNDATION

o Assistance Amount

$7,200 per year. Patients may apply for a second grant during their eligibility period subject to availability of funding.

o Eligibility Criteria:

- The patient must be getting treatment for hepatitis C.
- The patient must have health insurance that covers his or her qualifying medication or product.

- The patient's medication or product must be listed on PAN's list of covered medications.
- The patient's income must fall at or below 500% of the Federal Poverty Level.
- The patient must reside and receive treatment in the United States or U.S. territories. (U.S. citizenship is not a requirement.)

o LIST OF MEDICAITONS COVERED IN THIS PROGRAM:

- Copegus (ribavirin)
- Daklinza (daclatasvir dihydrochloride)
- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)
- Infergen (interferon alfacon-1)
- Intron A (interferon alfa-2b,recomb.)
- Mavyret (glecaprevir/pibrentasvir)
- Moderiba (ribavirin)
- Olysio (simeprevir sodium)
- Pegasys (peginterferon alfa-2a)
- Rebetol (ribavirin)
- Ribasphere (ribavirin)
- Ribatab (ribavirin)
- Ribavirin (ribavirin)
- Sovaldi (sofosbuvir)
- Sylatron (peginterferon alfa-2b)
- Technivie (ombitasvir/paritaprevir/ritonavir)
- Viekira Xr (ombitasvir/paritaprevir/ritonavir/dasabuvir sodium)
- Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
- Xifaxan (rifaximin)
- Zepatier (elbasvir/grazoprevir)

o CONTACT INFORMATION:

Toll free: 866-316-7263

o Link to online application:

https://panfoundation.org/index.php/en/patients/assistance-programs/hepatitis-c

ACCESSING DAA's THROUGH PRIVATE INSURERS

Refer to general information section (page 6)

ACCESSING DAA's THROUGH MEDICAID.

o Eligibility Criteria:

- Patient is enrolled in Texas Medicaid and is greater than or equal to 18 years of age.
- Patient has a diagnosis of chronic hepatitis C virus (HCV) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5, or 6.
- Genotype test results must be obtained within the previous 5 years from the date of prior authorization request.
- Immediate treatment is assigned the highest priority for patients with advanced fibrosis (Metavir stage F3) or cirrhosis (Metavir stage F4), liver transplant recipients, and patients with hepatocellular carcinoma. Patients with Metavir scores less than stage 3 may not be approved.
- Prescriber should be a Board Certified Gastroenterologist, Hepatologist, or Infectious Disease physician. A prescriber other than the above specialists may prescribe and assume responsibility and care for the patient when the prescriber is supervised by a specialist, or with consult from a specialist from the previous 90 days. A copy of written consult must be submitted. Exceptions may be considered when a specialist is not available.
- Required laboratory values in Section 3 of the prior authorization form must be obtained within 90 days prior to the request for HCV treatment.
- Q80K polymorphism testing is required for requests for treatment with Olysio within the previous 2 years.
- NS5A resistance testing is required for requests for treatment with Daklinza or Zepatier in genotype 1a patients within the previous 2 years.
- Child-Turcotte-Pugh Score must be assessed within 90 days prior to the request for HCV treatment.
- Female patients' pregnancy status must be determined by a pregnancy test prior to the request for HCV treatment. The pregnancy test should be conducted as close to the start of treatment as possible, but no later than 90 days prior to the request. Pregnancy status must be confirmed negative for all ribavirin containing regimens. Pregnancy status is not required for age greater than 50, or for those documented as not able to become pregnant.
- Patient must have one drug screening within 90 days prior to the request for HCV treatment.
- Patient must be assessed for hepatitis B coinfection within 90 days prior to the request for HCV treatment.
- Prescriber must provide required lab results at baseline, and treatment weeks 4 and 12.
- Documentation of any additional supporting labs must be provided if requested by the patient's health care plan.

o Treatment approval

- Prior authorization is granted for 6 weeks per approval. A request using the Antiviral Agents for Hepatitis C Virus Prior Authorization Form-Refill Request should be submitted by 6 weeks, and every 6 weeks thereafter of therapy to facilitate continuation of therapy.
- Prescriptions may be dispensed for a maximum 28 day supply.
- Refill authorization is subject to approval based upon submission of labs at weeks 4 and 12. Request for refill prior authorization may be rejected if patient or prescriber are unable to provide the required labs.
- Request for products other than a preferred product will require additional justification, including rational for why a preferred product is not indicated for the patient. Request for a product other than a preferred product does not guarantee approval.

o Link to Texas Medicaid Prior Authorization form for Hep C

https://hhs.texas.gov/laws-regulations/forms/1000-1999/form-1335-antiviral-agents-hepatitis-c-virus-initial-authorization-request-medicaid

View/search current Texas Medicaid formulary (updated quarterly) at www.txvendordrug.com

o Non-preferred Prior Authorization and Clinical Prior Authorization

Texas Medicaid (traditional & managed) utilizes two prior authorization (PA) programs: non-preferred prior authorization & clinical prior authorization. Non-preferred PA process is used when a preferred agent fails or if the patient has an allergic reaction or contraindication to a preferred agent. The clinical prior authorization process may also be required to ensure appropriate use of the preferred or non-preferred agent.

As of March 9, 2018:

Preferred	Non-Preferred	NP	C
Pegylated Interferons			
PegIntron (pegylated INF alfa-2b)	Pegasys (pegylated IFN alfa-2a)	X	
Polymerase/Protease Inhibitors			
Epclusa Mavyret Vosevi	Daklinza Harvoni Olysio Sovaldi Technivie Viekira Pak Viekira XR Zepatier	X	X
Ribavirin			
ribavirin caps/tabs	Rebetol solution Ribasphere 400 or 600 mg tabs ribavirin dose pack	X	

NP = Non-preferred PA applies
C = Clinical PA applies

For reference, fee-for-service Medicaid will give priority to patients with Metavir stage F3 or F4, liver transplant recipients, or those with hepatocellular carcinoma. Patients with Metavir score less than stage 3 may not be approved.

o Non-preferred PA:

STEP 1: Has the client been stable on 1 non-preferred agent for 30 days in the past 180 days? Yes – approved for 365 days; No – go to step 2.
STEP 2: Has the client failed a 30-day treatment trial with at least 1 preferred agent(s) within the past 180 days? Yes – approved for 365 days; No – go to Step 3.

STEP 3 : Is there a documented allergy or contraindication to preferred agents in this class? Yes – approved for 365 days; No – Request denied.

o Clinical PA

Must submit Antiviral Agents for Hepatitis C Virus Initial Authorization Request (Medicaid):

- Must submit Prescriber certification signed by the patient and prescriber (Form 1335, Part II; pg 2-3).
- Include documentation of Metavir score (biopsy in past 5 years OR FibroSURE, Fibrospect, Fibrometer, Fibroscan, or Sheer Wave Elastography in past 2 years).
- Include documentation of consult if applicable

Additionally, medical documentation on the form requires the following information be completed (within the allowable time frame) prior to date of PA submission:

-Genotype testing (within past 5 years)
-Metavir score (within past 2 years) or biopsy (within past 5 years)
-Polymorphism and/or resistance testing (if applicable, within past 2 years)
-Additional items within past 90 days:
-drug screen results
-alcohol abuse screening
-pregnancy testing
-Hepatitis B co-infection assessment
-Child-Turcotte-Pugh score
-Labs (ALT, AST, AlkPhos, CrCl, SCr, TBili, Hgb, Hct, INR, Plt, RBC, Alb, HCV RNA)

- Refill requests must be submitted every 6 weeks in order to continue therapy. Additionally, labs listed above must be collected at week 4 and week 12 of treatment for refill approval. Use Form 1336 for refills found here: https://hhs.texas.gov/laws-regulations/forms/1000-1999/form-1336-antiviral-agents-hepatitis-c-virus-refill-authorization-request-medicaid.

o Additional Considerations

- Patient's non-adherence to therapy for more than 14 days may result in discontinuation of prior authorization and additional refills may not be approved. Exceptions are considered in circumstances that are beyond patient or prescriber control. Documentation stating reason for gaps in therapy may be required at the request of the health plan.
- Patients requiring retreatment will be assessed for approval on a case by case basis.
- Lost or stolen medications may not be replaced.
- For appeals and reconsiderations, dates of any test and/or laboratory results that fall outside of the required
    - windows for submission will be considered valid if the date of the test and/or laboratory results were within the required window for submission at the time of the initial HCV prior authorization request. This policy is not applicable if more than 90 days have passed since the initial HCV prior authorization request.
- HCV viral load is recommended at 12 weeks following completion of therapy. Prescribers should obtain and maintain records of viral load at 12 weeks after completion of therapy

MEDICAID PRIOR AUTHORIZATION CHECK LIST

Eligibility		
Check	**Item**	**Timeline**
☐	Patient is enrolled in Texas Medicaid and is greater than or equal to 18 years of age.	
☐	Patient has a diagnosis of chronic hepatitis C virus (HCV) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5, or 6.	
☐	Genotype test result	5 years from date of prior authorization request
☐	Prescriber, Board Certified Gastroenterologist, Hepatologist or Infectious Disease physician	
☐	Laboratory values	Within 90 days prior to the request for HCV treatment
☐	Required lab values	Baseline, treatment weeks 4 and 12 (for refills)
☐	NS5A resistance testing for treatment with Daklinza or Zepatier in genotype 1a	Within the previous 2 years
☐	Child-Turcotte-Pugh Score	Within 90 days prior to treatment
☐	Pregnancy test (for female patients less than 50 years old)	Close to the start of treatment, but no later than 90 days prior to P/A request.
☐	Drug test	Within 90 days prior to request for HCV treatment
☐	Assessed for Hep B co-infection	Within 90 days prior to request for HCV treatment
☐	Refill request must be submitted	Every 6 weeks

o Non-preferred Prior Authorization

Check	Item	Timeline
☐	Patient stable on 1 non-preferred agent for 30 days in the past 180 days	
☐	Patient failed a 30 day treatment trial with at least 1 preferred agent(s) within the past 180 days	
☐	Is there a documented allergy or contraindication to preferred agents in this class	

o Clinical Prior Authorization

Check	Item	Timeline
☐	Form 1335, Part II page 2-3	
☐	Metavir score	Within past 2 years
☐	Biopsy or one of the following non-invasive tests FibroSURE, Fibrospect, Fibrometer, Fibroscan, or Sheer Wave Elastography.	Biopsy - within past 5 years; Non invasive – within the past 2 years

☐	Polymorphism and/or resistance testing – if applicable to drug choice (Olysio, Daklinza, Zepatier)	Within past 2 years
☐	Drug screen results	Within past 90 days
☐	Alcohol abuse screening	Within past 90 days
☐	Pregnancy testing	Within past 90 days (close to treatment start)
☐	Hepatitis B co-infection assessment	Within past 90 days
☐	Child-Turcotte-Pugh score	Within past 90 days
☐	*Labs	Within past 90 days
☐	Refill request must be submitted	Every 6 weeks
☐	*Labs	At weeks 4 and 12 for refill approval
☐	Form 1336 for refills	

*alkaline phosphatase, aspartate transaminase, alanine aminotransferase, albumin, total bilirubin, serum creatinine, creatine clearance, international normalized ratio, platelet count, red blood cell count, HCV RNA viral load