Strategies for Addressing Medicaid and Other Insurers' Prior Authorization Requirements for Hepatitis C Direct Acting Antiretrovirals (DAAs)

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May 30, 2018

Roles of Pharmacists in HCV Management

- Consultant for HCV
- Aid in medication selection/ verify treatment
- Work with payors and patient assistance programs to ensure coverage
- Drug-drug interaction screening and management
- Patient management/ education
- Liaison for medication assistance programs and specialty or dispensing pharmacies
- Refill management

Pharmacist Impact in HCV Care

- Implementing HCV screening
- Treating patients under protocol: Veterans Affairs, Academic Institutions
- Indian Health Services
  - Establishing HCV clinics to treat patients
    - Montana
    - Cherokee Nation
  - Great Plains HCV ECHO

New Mexico Pharmacist Clinician

- Prescriptive authority
  - Guidelines or protocol submitted to Board of Pharmacy with practitioner granting prescriptive authority within scope of practice
  - Licensing requirements:
    - 60-hour physical assessment course
    - 150 hour, 300 patient contact preceptorship supervised by physician or practitioner with prescriptive authority

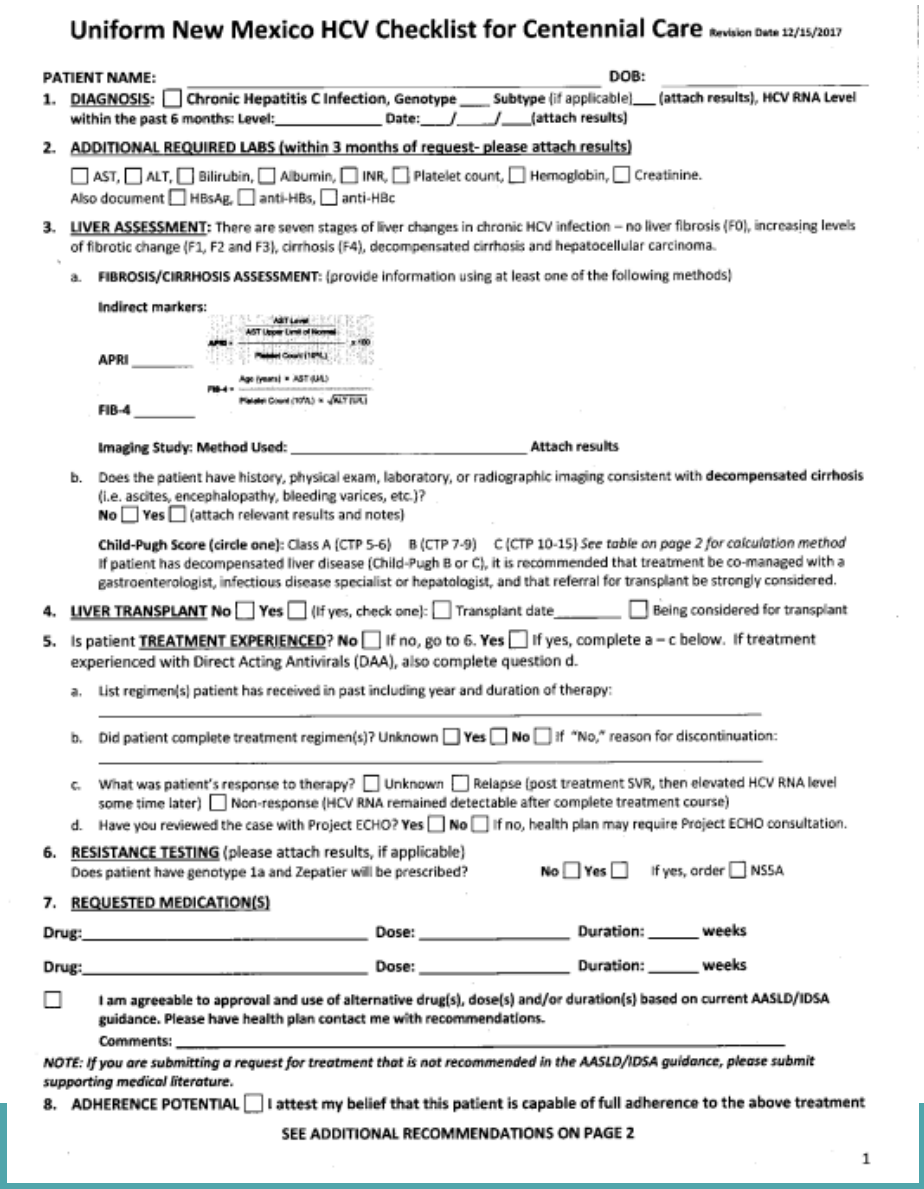
Role of Pharmacist Clinician in HCV Management

- Drug-drug interaction review
- Initial evaluation
- Counsel on HCV transmission/ reinfection risks
- Perform physical exam
- Order labs/imaging
- Order vaccinations
- Prescribe HCV medications
- Follow patients through HCV therapy
- Adjust medications as needed through HCV treatment

HCV Treatment Access in New Mexico

- Prescriber Restrictions
  - None
- Liver Damage Restrictions
  - None
- Sobriety Restrictions
  - None
  - Referral for counseling and substance use treatment but coverage cannot be denied for active use

New Mexico Uniform HCV Checklist



Uniform New Mexico HCV Checklist for Centennial Care Revision Date 12/15/2017

PATIENT NAME: _____ **DOB:** _____

1. **DIAGNOSIS:** ☐ **Chronic Hepatitis C Infection, Genotype** ____ **Subtype** (if applicable)___ **(attach results), HCV RNA Level within the past 6 months: Level:**_____ **Date:**___/___/___**(attach results)**
2. **ADDITIONAL REQUIRED LABS (within 3 months of request- please attach results)**
   ☐ AST, ☐ ALT, ☐ Bilirubin, ☐ Albumin, ☐ INR, ☐ Platelet count, ☐ Hemoglobin, ☐ Creatinine.
   Also document ☐ HBsAg, ☐ anti-HBs, ☐ anti-HBc
3. **LIVER ASSESSMENT:** There are seven stages of liver changes in chronic HCV infection – no liver fibrosis (F0), increasing levels of fibrotic change (F1, F2 and F3), cirrhosis (F4), decompensated cirrhosis and hepatocellular carcinoma.
   a. **FIBROSIS/CIRRHOSIS ASSESSMENT:** (provide information using at least one of the following methods)
      Indirect markers:
      APRI _____
      FIB-4 _____
      Imaging Study: Method Used: _____ **Attach results**
   b. Does the patient have history, physical exam, laboratory, or radiographic imaging consistent with **decompensated cirrhosis** (i.e. ascites, encephalopathy, bleeding varices, etc.)?
      No ☐ **Yes** ☐ (attach relevant results and notes)
      Child-Pugh Score (circle one): Class A (CTP 5-6) B (CTP 7-9) C (CTP 10-15) *See table on page 2 for calculation method*
      If patient has decompensated liver disease (Child-Pugh B or C), it is recommended that treatment be co-managed with a gastroenterologist, infectious disease specialist or hepatologist, and that referral for transplant be strongly considered.
4. **LIVER TRANSPLANT No** ☐ **Yes** ☐ (If yes, check one): ☐ Transplant date_____ ☐ Being considered for transplant
5. Is patient **TREATMENT EXPERIENCED**? **No** ☐ If no, go to 6. **Yes** ☐ If yes, complete a – c below. If treatment experienced with Direct Acting Antivirals (DAA), also complete question d.
   a. List regimen(s) patient has received in past including year and duration of therapy:
      _____
   b. Did patient complete treatment regimen(s)? Unknown ☐ **Yes** ☐ **No** ☐ If "No," reason for discontinuation:
      _____
   c. What was patient's response to therapy? ☐ Unknown ☐ Relapse (post treatment SVR, then elevated HCV RNA level some time later) ☐ Non-response (HCV RNA remained detectable after complete treatment course)
   d. Have you reviewed the case with Project ECHO? **Yes** ☐ **No** ☐ If no, health plan may require Project ECHO consultation.
6. **RESISTANCE TESTING** (please attach results, if applicable)
   Does patient have genotype 1a and Zepatier will be prescribed? **No** ☐ **Yes** ☐ If yes, order ☐ NS5A
7. **REQUESTED MEDICATION(S)**

Drug:_____ **Dose:** _____ **Duration:** _____ **weeks**

Drug:_____ **Dose:** _____ **Duration:** _____ **weeks**

☐ **I am agreeable to approval and use of alternative drug(s), dose(s) and/or duration(s) based on current AASLD/IDSA guidance. Please have health plan contact me with recommendations.**

Comments: _____

NOTE: If you are submitting a request for treatment that is not recommended in the AASLD/IDSA guidance, please submit supporting medical literature.

8. **ADHERENCE POTENTIAL** ☐ **I attest my belief that this patient is capable of full adherence to the above treatment**

SEE ADDITIONAL RECOMMENDATIONS ON PAGE 2

1

- HCV labs within 6 months
- Other labs within 90 days

Available at:

http://www.hsd.state.nm.us/providers/uniform-new-mexico-hcv-checklist-for-centennial-care-revision-date-12-15-2017.pdf

HCV Treatment Outcomes

- Among 601 patients treated through Project ECHO with complete data from Jan 2015-July 31, 2017:
  - SVR >95%

Challenges

- In NM
  - Increasing screening/testing for HCV
  - Varied access for HCV among commercial plans
- For our partners, state of residence is a key variable in HCV treatment
  - Requirements for liver biopsy
  - Requirements for liver disease severity
  - Sobriety restrictions
    - Need for recovery services
    - Urinalysis
  - Prescriber restrictions