SPECIAL TRIBAL CONSULTATION TELECONFERENCE

Date: September 8, 2016
Time: 1:00 PM-2:00 PM Arizona Time
Conference Call-In: 1-877-820-7831 Participant Passcode: 992862

NOTIFICATION TO TRIBES

Good Morning!

This is to inform you that a special AHCCCS Tribal Consultation teleconference is scheduled for **September 8, 2016 from 1:00-2:00 p.m.** (AZ time) to discuss the proposed changes to the Hepatitis C Criteria for Direct Acting Antiviral medications (HCV Policy 320=N). These medications include Sovaldi, Harvoni, Technivie, Daklinza, Zepatier, Viekira, Olysio and Epclusa. Pharmacists, prescribing clinicians, nurses or other clinicians are encouraged to participate in this meeting for updated information. The call in number is, **1-877-820-7831,** enter **participant passcode**, **992862#.** The draft agenda is attached. If you have questions prior to or following the conference call please contact, Suzanne.berman@azahcccs.gov or 602-417-4726.

Please place this important date on your calendars. We look forward to your participation

Sincerely,
Bonnie

Bonnie Talakte
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AGENDA

The purpose of the meeting is to discuss the proposed changes to the Hepatitis C Criteria for Direct Acting Antiviral medications. These medications include Sovaldi, Harvoni, Technivie, Daklinza, Zepatier, Viekira, Olysio and Epclusa.

TOPIC	LEAD
1:00 p.m. - Welcome & Introductions	Suzanne Berman, AHCCCS Director of Pharmacy Services
1:20 p.m.- Hepatitis C Criteria for Direct Acting Antiviral Medications (HCV Policy 320-N)	Suzanne Berman
2:00 p.m. - Adjourn	

ATTENDEES

AHCCCS Representatives	Suzanne Berman Theresa Gonzales Robin Davis
Other	Alithia Gabrellas- Ft. Defiance Jim McCauley- White River Amy Nguyen- White River Jeff Walling- PIMC Brigg Reilley- IHS HQ Violet Skinner- Tuba City Heather Huddleman- Paul Bloomquist Carol Chicharello- Phoenix area IHS Eric G- Winslow Nate V- Colorado River

MEETING SUMMARY

Hepatitis C Criteria for Direct Acting Antiviral Medications (HCV Policy 320-N)

- Alma Torres provided a draft copy of the proposed changes to policy 320-N to the attendees.
- Suzi Berman reviewed the draft Hepatitis C coverage policy line by line with the attendees and noted the proposed changes. The changes include:
  - Updated Description
  - Changes to Amount, Duration and Scope
    - Liver Fibrosis score requirement changed from F3 to F2. Diagnosis must be evidenced by biopsy, Fibroscan, Elastography, Fibrosure/FibroTest Acti-Test level, or APRI (described in Table 1 on document)/or
    - Members who have one of the conditions below, regardless of fibrosis level
      - Member is recently post liver transplant
      - Member is diagnosed with State I-III Hepatocellular Carcinoma meeting Milan Criteria
      - Member is diagnosed with Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
      - Member is diagnosed with HCV induced renal disease
      - Member is diagnosed with leukocytoclastic vasculitis

Table 1 (new)

Metavir Score	Biopsy	Fibroscan	Elastrography (ARFI/PSWE)	Fibrosure/ FibroTest Acti-Test	APRI
F4	F4	> 12.5 kPa	> 2.34 m/s	> 0.75	> 2.0
F3	F3	9.6 – 12.4 kPa	2.01 – 2.33 m/s	0.58 – 0.74	1.5 – 1.9
F2	F2	7.1 – 9.5 kPa	1.38 – 2.0 m/s	0.49 – 0.57	1.0 – 1.4
F1/0	F1/0	< 7.0 kPa	< 1.37 m/s	< 0.48	< 0.9

	▪ Member must receive at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member has evidence of laboratory immunity. ▪ If a member has a substance abuse disorder in the past 12 months from the requested date for treatment, the member must be in remission for the past three months from the requested date for treatment and must be engaged in a substance use disorder treatment program at the time of the prior authorization request and over the course of treatment if the HCV medications are approved. o Treatment Monitoring Requirements ▪ Members prescribed HCV treatment must participate in a treatment adherence program. ▪ At a minimum, providers are responsible for completing HCV viral load laboratory testing at weeks 4, 12, and 24 for members approved for 12 week HCV regimens ▪ Ata a minimum, providers are responsible for completing HCV viral load laboratory testing at 4, 12, 24, and 48 for members approved for 24 week HCV regimens ▪ Providers are required to monitor hemoglobin levels periodically when the member is prescribed ribavirin. o Limitations ▪ HCV coverage is not provided for the following: • Monotherapy of Daklinza, Olysio or Sovaldi; • Sovaldi for greater than 24 weeks of therapy; • Direct acting antiviral dosages greater than the FDA approved maximum dosage; • Ombitasvir, Paritaprevir and Tritonavir or Ombitasvir, Paritaprevir and Ritonavir; Dasabuvir tablets shall not be approved for members whose Child Pugh score is B or C; • Grazoprevir/elbasvir if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request; • Members when there is a documented non-adherence to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures; • Members declining to participate in a treatment adherence program; • Members with decompensated liver disease; • Members whose comorbidities are such that their life expectancy is one year or less; • Members currently using a potent P-gp inducer drug; • Greater than one course of therapy per lifetime; • Lost or stolen medication absent of good cause; • Fraudulent use of HCV medications. ▪ Required Documentation for submission of HCV Prior Authorization requests include: • Evidence of liver fibrosis ; • HCV treatment history and responses; • Evidence of Hepatitis A &B vaccinations or lab evidence of

	immunity; • Current medication list; • Laboratory results for all of the following: o HCV screen, genotype and current baseline viral load, total bilirubin, albumin, INR, CrCl or GFR, LFTs, CBC and drug/alcohol screen completed within the last 90 days.
Questions/ Answers/ Comments	1. What APRI score is equivalent to F2? a. 1.0-1.4 2. Is the policy available online? a. Not at the current time. The policy will be presented to the AHCCCS Policy Committee then will be posted. 3. What was the previous APRI requirement? a. There was not an APRI requirement previously. 4. Was there any thought given to why it has to be prescribed by a specialist? a. There have been cases where hepatocellular carcinoma has been missed. The ECHO program is available throughout the state and Dr. Manch consults for several IHS and 638 facilities. 5. Is the patient required to be seen in person by a specialist? a. No- the consultation can be done through the ECHO program. 6. What documentation is required to submit with the PA for the consultation? Is the ECHO summary adequate? a. Yes, the ECHO summary is adequate. 7. Will a consultation with UCSF work? a. Please send more information to Suzi on this program. 8. Is this meeting informational only, or are comments requested? a. The policy will be posted on the AHCCCS website. Comments may be submitted when the policy is posted on the website, or they can be emailed to Suzanne.Berman@azahcccs.gov . 9. There are currently 3000 patients who may require treatment. Having the specialist requirement could potentially cause a bottleneck with patients waiting for consultation. a. Please submit comments for consideration. 10. A patient was recently denied treatment because they were not in consultation with an HIV specialist, but did not have HIV. a. Please bring any concerns like this to our attention for review; we review all concerns. 11. ASLD recommends treatment for members with decompensated cirrhosis. The average lifespan for someone not treated is 3 years, but if treated, could become compensated again. There would be much improvement if treated. There was a situation where a patient on the transplant list was declined coverage. Because of this they would have received a transplant untreated and infect the new liver. a. Please submit these concerns and comments for consideration. 12. Is the life expectancy of 1 year or less for hepatitis only or any condition? a. This would be for any condition. 13. Is prior authorization for this medication required for AIHP members from IHS and 638 prescribers? a. Typically, the IHS and 638 facility pharmacies not provided these medications due to cost. It is be up to them if they would like to cover these agents under the AIR, but currently it is not believed that they are covering them at this

	time. Prior Authorization is required when the drug will filled at one of the OptumRx network pharmacies that is not an IHS or 638 pharmacy. 14. Regarding substance abuse- Wondering if the better way to phrase this would be to deny treatment for substance abuse issues that would interfere with therapy. If they can complete therapy, the drug use should be unrelated. We would not deny coverage to someone with drug resistant TB if they are wrestling with a Heroin addiction. a. After consulting with the hepatologist, it was communicated to us that they do not treat patients with active current illicit IV drug use due to risky behaviors. Please post or send comments for consideration. 15. Regarding the one treatment for lifetime exclusion. We had a patient followed the treatment but fell within the 5% that did not improve. Is this a situation where retreatment could be considered? a. Providers can always request an exception. Please post or send your comments, we will welcome them. 16. When and where should comments be sent? a. Please email to Suzi Berman (Suzanne.Berman@azahcccs.gov) by September 22, 2016. 17. What pharmacies provide the medications? a. HCV medications are provided to AIHP (Fee-For-Service) members by Avella or BriovaRX Pharmacies. 18. Please consider making exceptions for members waiting for liver transplant. a. Please submit this in writing for consideration.
	Meeting Adjourned at 1:45 p.m.