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Date: December 15, 2017

Subject: Changes to treatment guidance for chronic Hepatitis C virus (HCV) infection

Effective December 15, 2017, Centennial Care MCOs are directed to approve properly requested treatments for the following Centennial Care members with chronic HCV infection:

1. All members over age 17, all HCV genotypes, with a positive Hepatitis C RNA level
2. Note that in all cases MCOs are directed to ensure (using the AASLD/IDSA guidelines) that each treatment request is appropriate with respect to:
 - a. HCV genotype and viral load
 - b. Drug dose(s) and duration(s). Note that the MCOs preferred formulary agent may be given preference if the level of evidence and effectiveness (as measured by SVR) is equal or greater, and no drug interactions are of concern
 - c. The presence or absence of advanced fibrosis or cirrhosis. For the purpose of making treatment decisions using the AASLD/IDSA guidance, "cirrhosis" can be considered to be present if any of the following are present:
 - i. APRI ≥ 1.0 ¹
 - ii. Fib-4 ≥ 3.25 ²
 - iii. Transient Elastography Score ≥ 12.5 kP³ (F4 equivalent)
 - iv. Fibrotest ≥ 0.73 ⁴ (F4 equivalent) OR Fibrometer with F4 predominance
 - v. Radiographic imaging or physical exam findings consistent with cirrhosis
 - vi. Liver biopsy confirming a METAVIR Score of F4
 - d. Prior HCV treatment experience.
 - i. Plans may require resistance-associated substitutions (RASs) testing, based on AASLD guidance
3. MCOs shall, by December 31, 2017, contact members (and their requesting providers) who now meet the above treatment criteria, but were previously denied treatment, for reconsideration of their HCV treatment requests. Also, by January 30, 2018, submit a report to MAD documenting the results of this process.

4. MCOs are directed to work to expedite the handling of all treatment requests using the “Uniform New Mexico HCV Checklist for Centennial Care” (attached). The header of this form may be adapted to make it specific to your organization.
5. Guidance regarding lost or stolen medications:
 - a. MCOs are directed to use the same criteria currently used for refills of other lost or stolen medications
 - b. MCOs are directed to use Care Coordination and other functions to minimize this occurrence (see below)
6. Guidance regarding requests for off-label, experimental, and other forms of treatment that are not specified in the guidelines
 - a. MCOs are directed to initiate a peer to peer consultation with the requesting physician to further understand the request and its rationale
 - b. MCOs are directed to present the case to Project ECHO before issuing a denial
7. Note that a “properly requested treatment” as defined above means that:
 - a. The checklist form is completed fully as directed and submitted
 - b. Necessary lab data and copies of medical records are attached
 - c. The requested drug(s), dose(s), and length of treatment are consistent with AASLD/IDSA guidance as written (the level of evidence in the guidance should not be considered relevant to length of treatment decisions). If not consistent, the MCO is directed to provide an appropriate alternative.
8. MCOs are granted the option to expand their treatment criteria beyond these guidelines (e.g., to those 17 years of age and under), with advance notice to and approval by the Medical Assistance Division.

MCOs are further directed to:

1. Develop a provider incentive plan to expand the number of practitioners treating chronic HCV in New Mexico, including:
 - a. Incentive(s) to receive training in the treatment of chronic HCV infection
 - b. Incentive(s) to begin treating such patients
 - c. Incentive(s) for treatment of each patient
2. Not use active alcohol or drug use as screening criteria for treatment approval or denial
3. Not use the specialty of the requesting provider as screening criteria for treatment approval or denial. If an MCO receives multiple requests from a provider that are not genotype-drug-length of treatment appropriate, the provider should be encouraged to use Project ECHO.
4. Refer all members to a community health worker, care coordinator, or MCO specialty pharmacist at the time of drug treatment **request** in order to:
 - a. make verbal contact directly with the member
 - b. help expedite obtaining and submitting all necessary studies for an authorization decision
 - c. help explain the Plan’s decision to the member
 - d. help coordinate receipt of medications and enhance treatment adherence

- Note that these treatment functions can be performed by, or in concert with, other Plan-contracted care coordination efforts (e.g., PBM or drug manufacturer)
5. Submit quarterly data concerning number of requests, approvals, and denials by fibrosis stage (or equivalent) and genotype for all member treatment requests.
 - a. MAD will supply revised spreadsheets for completion.
 - b. MCOs are also directed to calculate the quarterly number of members treated compared to their quarterly target, and to submit a corrective action plan within 45 days of the end of the quarter if the gap of actual members treated is > five percent below the quarterly target.
 6. Send a representative to attend quarterly meetings with other MCOs and MAD representatives as part of the ongoing HCV Workgroup to review current data and recent guidance revisions and propose evidence-based future revisions to treatment guidelines.
 7. Continue to implement a comprehensive plan of outreach to the Plan's referring providers requesting oral drug treatment for chronic HCV-infected patients, including
 - a. Use of a common "Hepatitis C Treatment Packet," whose purpose is to recruit, educate and assist new providers in treating Hepatitis C in their patients
 - b. A plan to educate providers on the use of the revised "Uniform New Mexico HCV Checklist for Centennial Care" (attached)
 - c. Clarification of new treatment guidelines
 - d. Clarification of prior authorization processes
 - e. Use of Project ECHO review for:
 - i. Any provider needing assistance on any case, and
 - ii. All cases for which retreatment (after prior all-oral therapy) is being requested and the MCO feels such a review would benefit the member
 8. Implement a comprehensive plan to expand HCV case finding efforts screening efforts, including:
 - a. Use of claims database to identify patients with higher probability of HCV infection (e.g., members who have claims for HCV genotype or HCV RNA viral load testing)
 - b. Collaboration with the NM Department of Health to identify infected members
 - c. Screening of members post-incarceration
 - d. Collaborating with providers engaged in the treatment of active drug users
 9. Continue to implement a comprehensive plan to expand HCV screening efforts to conform to USPSTF/CDC/AASLD/IDSA guidelines (listed below), including:
 - a. Outreach to contracted providers
 - b. Outreach to members who are recommended for screening
 - c. Collaboration with contracted laboratories to aid in case identification
 - d. Guidelines for screening:

- i. One-time HCV testing is recommended for persons born between 1945 and 1965, without prior ascertainment of risk.
- ii. Other persons should be screened for risk factors for HCV infection, and one-time testing should be performed for all persons with behaviors, exposures, and conditions associated with an increased risk of HCV infection.
 - 1. *Risk behaviors*
 - a. Injection-drug use (current or ever, including those who injected once)
 - b. Intranasal illicit drug use
 - 2. *Risk exposures*
 - a. Long-term hemodialysis (ever)
 - b. Getting a tattoo in an unregulated setting
 - c. Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-infected blood
 - d. Children born to HCV-infected women
 - e. Prior recipients of transfusions or organ transplants, including persons who:
 - i. were notified that they received blood from a donor who later tested positive for HCV infection
 - ii. received a transfusion of blood or blood components, or underwent an organ transplant before July 1992
 - iii. received clotting factor concentrates produced before 1987
 - iv. Persons who were ever incarcerated
 - f. Other
 - i. HIV infection
 - ii. Unexplained chronic liver disease and chronic hepatitis including elevated alanine aminotransferase levels
 - iii. Solid organ donors

¹ Lin ZH, Xin YN, Dong QJ, et al. Performance of the aspartate aminotransferase-to-platelet ratio index for the staging of hepatitis C-related fibrosis: an updated meta-analysis. *Hepatology*. 2011;53:726-36. In a meta-analysis of 40 studies, investigators concluded that an APRI score greater than 1.0 had a sensitivity of 76% and specificity of 72% for predicting cirrhosis. In addition, they concluded that APRI score greater than 0.7 had a sensitivity of 77% and specificity of 72% for predicting significant hepatic fibrosis. See APRI calculator at www.hepatitisc.uw.edu (click on Clinical Calculators tab and then APRI Calculator). Note also that this is the numeric threshold used by NM Project ECHO.

² Sterling RK, Lissen E, Clumeck N, et. al. Development of a simple noninvasive index to predict significant fibrosis patients with HIV/HCV co-infection. *Hepatology* 2006;43:1317-1325. Using a lower cutoff value of 1.45, a FIB-4 score <1.45 had a negative predictive value of 90% for advanced fibrosis (Ishak fibrosis score 4-6 which includes early bridging fibrosis to cirrhosis). In contrast, a FIB-4 >3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis. In the patient cohort in which this formula was first validated, at least 70% patients had values <1.45 or >3.25. See FIB-4 calculator at www.hepatitisc.uw.edu. Click on Clinical Calculators and then FIB-4 Calculator. Note also that this is the numeric threshold used by NM Project ECHO.

³ van du Putte, op. cit. See page 470, column b.

⁴ Rossi E, Jeffrey G, et al. Validation of the FibroTest Biochemical Markers Score in Assessing Liver Fibrosis in Hepatitis C Patients. *Clinical Chemistry*, 2003;49(3):450-454.