NEW YORK STATE | Department of Health | Office of Health Insurance Programs

Prior Authorization of Hepatitis C Medications in NYS Medicaid Fee for Service (FFS) and Medicaid Managed Care

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Background on Medicaid Redesign Team, (MRT) 11 “Bundle Pharmacy into Managed Care”

- Effective 10/1/2011, approximately 3.7 million members in Medicaid/Family Health Plus managed Care Plans began receiving their pharmacy benefit through their plans.
- Key MRT Phase 1 Initiative
- Aligned with overall MRT strategy of “care management for all.”

Background on MRT 11 “Bundle Pharmacy into Managed Care” Continued..

- Managed Care plans were allowed to follow their own formularies (had to provide a similar benefit to FFS)
- Managed Care plans were allowed to develop their own prior authorization (PA) criteria
- The Managed Care PA process is governed by Federal Law, State Law and the Model Contract
    - Federal Law- 42 CFR 438
    - State Law- NYS Public Health Law §4408-a and Article 49 and 10 NYCRR Part 98
    - Medicaid Managed Care/Family Health Plus/HIV SNP Model Contract- Appendix F

    https://www.health.ny.gov/health_care/managed_care/providers/#model_contracts

Background on PA in FFS

- Federal legislation that requires states to implement Drug Utilization Review (DUR) programs also requires states to establish DUR boards (DURB) whose function is to play a major role in each state's Medicaid Fee-for Service (FFS) DUR program.
- Responsibilities of the DURB include:
  - ✓The establishment and implementation of medical standards and criteria for the retrospective and prospective DUR program.
  - ✓The development, selection, application, and assessment of educational interventions for physicians, pharmacists and recipients that improve care.
  - ✓**The collaboration with managed care organizations to address drug utilization concerns and to implement consistent management strategies across the fee-for-service and managed care pharmacy benefits**.
  - ✓The review of therapeutic classes subject to the Preferred Drug Program.

Note: Medicaid managed care plans also perform these activities through their Pharmacy and Therapeutics (P&T) Committees who perform similar functions.

Hepatitis C Workgroup

- Meetings began in May of 2014 to discuss Hepatitis C Virus (HCV), treatment advances (Solvaldi), updated guidelines, impact and options.
- Workgroup consisted of Department of Health policy and rate staff, the AIDs Institute, Managed Care plans and representatives from the provider community.

Goal:

- ✓ Develop standardized criteria to be used across FFS and MC

Outcome

- The work group was able to achieve a consensus on a majority of the criteria
- Some areas which there we mixed opinion were:
  - ❖Patient readiness
  - ❖Disease severity
  - ❖Prescriber experience

- Managed Care plans voluntarily adopted all or parts of the criteria
- Medicaid FFS also reviewed the criteria at the September 18, 2014 DURB meeting and implemented the criteria on October 16,2014:

http://www.health.ny.gov/health_care/medicaid/program/update/2014/oct14_mu.pdf

FFS HCV Criteria Summary

- **FDA labeling and compendia supported use**
  - Verification of diagnosis, genotype, dosing and duration, etc.
- **Prescriber experience and training**
  - Prescribed by hepatologist, gastroenterologist, infectious disease specialist, transplant physician or health care practitioner experienced and trained in the treatment of HCV or a healthcare practitioner under the direct supervision of a listed specialist.

AND

  - Clinical experience is defined as the management at least 10 patients with HCV infection and treatment of 10 HCV patients in the last 12 months and at least 10 HCV- related CME credits in the last 12 months.

OR

  - Management and treatment of HCV infection in partnership (defined as consultation, preceptorship, or via telemedicine) with an experienced HCV provider who meets the above criteria

FFS HCV Criteria Summary Continued..

- **Patient readiness and adherence**
  - Evaluation by using scales or assessment tools readily available to healthcare practitioners at: http://www.integration.samhsa.gov/clinical-practice/screening-tools or https://prepc.org/ to determine a patient's readiness to initiate HCV treatment, specifically drug and alcohol abuse potential.
- **Disease Prognosis and Severity**
  - Evidence of Stage 3 or 4 hepatic fibrosis including one of the following: Liver biopsy confirming a METAVIR score F3 or F4 OR Transient elastography Fibroscan(®) score greater than or equal to 9.5 kPa; OR FibroSure(®) score of greater than or equal to 0.58; OR APRI score greater than 1.5; OR Radiological imaging consistent with cirrhosis (e.g. evidence of portal hypertension).

FFS HCV Criteria Summary Continued..

- Evidence of extra-hepatic manifestation of HCV, such as type 2 or 3 essential mixed cryoglobulinemia with end- organ manifestations (e.g. vasculitis), or kidney disease (e.g. proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis). Documentation of the presence of extra-hepatic manifestations based on lab results or imaging results (e.g. CBC, erythrocyte sedimentation rate (ESR)/ C-reactive protein (CRP), urinalysis, BUN/ creatinine and angiography) must be submitted.

OR

Liver Transplant
OR
HIV-1 co-infection
OR
HBV co-infection
OR
Other coexistent liver disease (e.g. nonalcoholic steatohepatitis)
OR
Type 2 diabetes mellitus (insulin resistant)
OR
Porphyria cutanea tarda
OR
Debilitating fatigue impacting quality of life
(e.g., secondary to extra-hepatic manifestations and/or liver disease)

HCV- Timeline

- The Medicaid FFS DURB met on November 20, 2014 to review the entire Hepatitis C therapeutic class, now including Harvoni.
  - It was decided to continue to use the clinical criteria as approved at the Sept. DURB meeting with Harvoni as nonpreferred.
- The DURB met February 26, 2015 to review the entire Hepatitis C therapeutic class, now including Viekira.
  - The DURB voted to make Viekira preferred and that Viekira be excluded from the HCV clinical criteria addressing disease prognosis and severity.
- When and in Whom to Initiate HCV Therapy- Updated October 22, 2015
  - "*Based on the evidence the panel recommends treatment for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy*"
- November 5, 2015- CMS release, assuring access to Medicaid members to Hepatitis C drugs. https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf

HCV Timeline Continued..

- The DURB met on April 27, 2016 to review the entire Hepatitis C therapeutic class, now including Daklinza, Technivie & Zepatier.
  - The DURB voted to make Daklinza, Harvoni, Technivie & Zepatier to be preferred.
  - The DURB voted to change the Direct Acting Antiviral clinical criteria. Disease prognosis and severity was eliminated. Clarification to MCO's- Patient Readiness and Adherence criteria does not include requirements for abstinence from alcohol or drug use.
- The DURB met on September 15, 2016 to review the entire Hepatitis C therapeutic class, now including Epclusa & Viekira XR.
  - The DURB voted to make Epclusa preferred for genotype 2 & 3, Viekira XR preferred & Solvaldi nonpreferred.
- The DURB met on October 19, 2017 to review the entire Hepatitis C therapeutic class, how including Mavyret & Vosevi.
  - The DURB voted to make Mavyret, Vosevi & Epclusa the preferred products. They nonpreferred additionally Daklinza, Harvoni, Technivie, Viekira/ Viekira XR and Zepatier.

HCV MCO Formulary/PA

- Some of the MC plans have also chosen preferred products and continue to update their criteria.
- The Department has worked with the MC plans on a PA checklist in an effort to standardize PA the process.
- The Department has also published a Hepatitis C Practitioner List and request form to help streamline the PA process. The list is available at: http://www.health.ny.gov/health_care/medicaid/program/dur/hepa_c_virus.htm

Formulary Information

- In Medicaid FFS all drugs are included on the formulary, if the manufacturer is a Federal rebate signer and the drug is not in an Federally excluded category.
  - Medicaid Formulary file search: https://www.emedny.org/info/formfile.aspx
  - Medicaid Prior Authorization Programs: https://newyork.fhsc.com/
- New York State Medicaid Managed Care and Family Health Plus Pharmacy Benefit Information Center: Formulary and Non-formulary drugs display via the drug look-up option and can also be found on the plan site under Medicaid covered drugs. http://mmcdruginformation.nysdoh.suny.edu/
  - All Managed Care Plans represented and specific information listed on site:
    - ✓General pharmacy benefit information (PA phone number for prescribers etc.)
    - ✓Medicaid covered drugs
    - ✓Standardized PA form
    - ✓Drug Look-up Option & Quick lists
    - ✓News & helpful links
    - ✓Frequently asked questions:
      - ❖Complaints
      - ❖Definitions
      - ❖Helpful links

Conclusion

- The Department continues to have correspondence with the MC plans on this topic and the pharmacy benefit as a whole.
- The Department and MC plans continue to try and leverage supplemental rebates from drug manufacturers.
- The Department continues to facilitate complaints with MC plans to assist with resolution.
- The Department continues to improve the PA process through automation and encourages the MC plans to do the same.

Reference Slide

- **New York State Medicaid Managed Care and Pharmacy Benefit Information Center: http://mmcdruginformation.nysdoh.suny.edu/**
- **NYS Medicaid FFS Prior Authorization Programs at: https://newyork.fhsc.com/**
- **NYS Medicaid Formulary File: https://www.emedny.org/info/formfile.aspx**
- **Medicaid FFS Questions/Complaints: ppno@health.state.ny.us**
- **Medicaid FFS DUR webpage: http://www.health.ny.gov/health_care/medicaid/program/dur/**
- **Medicaid FFS Pharmacy Program webpage: http://www.health.ny.gov/health_care/medicaid/program/pharmacy.htm**
- **Medicaid Redesign: http://www.health.ny.gov/health_care/medicaid/redesign/**