Michigan Medicaid and Hepatitis C Treatment

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MDHHS
Modern Hepatitis C Treatment

- Effective treatment for chronic Hepatitis C began with the development of the medication class called “Direct Acting Antivirals” or DAA
- Prior to that there was only marginal success with regimens that included interferon, ribavirin and oral protease inhibitors Victrelis (boceprevir) or Incivek (telaprevir). Regimens had very poor compliance.
- The first DAA was Gilead Pharmaceutical’s Sovaldi (sofosbuvir), approved in December 2013
American Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of America (IDSA) released a guidance document in January 2014 that included treatment with Sovaldi as the new standard of care.

- The cost of a course of Sovaldi varied by country.
- A treatment course in the US was $90,000 per patient while in Egypt it was $800 per patient.
- Impact on Medicaid programs necessitated many states to restrict coverage.
Michigan:

- Michigan Dept. of Health and Human Services (MDHHS) began negotiations for special Hepatitis C appropriation funding from the Michigan legislature to pay for the new Hepatitis C treatments
- Began covering Sovaldi on a case by case basis while awaiting legislative decision
Legislature approved funding in 2015 to begin treating chronic Hepatitis C patients with Metavir scores of F3-F4, those co-infected with HIV, had certain Hep C co-morbidities or who were status post liver transplant.

In addition, all potential patients had to be drug and alcohol free for 6 months.

Mandated an annual report, beginning March 2017, that detailed expenditures, coverage details of treatment approvals.
Current Coverage Criteria:

- Must be 18 years of age or older
  - Now indicated for pediatric patients >12 yo
- Diagnosis of chronic hepatitis
- RNA viral load must be documented prior to initiation of treatment
- Calculated Child-Pugh score must be documented.
- Genotype must be documented
patient must have one of the following:

- **HIV** co-infection
- Prior **liver transplant**
- Serious extra hepatic manifestation of hepatitis C (i.e. cryoglobulinemia, membranoproliferative glomerulonephritis)
- Metavir **fibrosis score of F2–F4** (expanded coverage to F2 in fall 2016) documented by one of the following:
  - Serum marker such APRI, FIB-4 or Fibrotest/Fibrosure
  - Fibroscan, Fibrospect or Shear Wave Velocity measurements
  - Liver biopsy
  - Cirrhosis, esophageal varices, ascites or splenomegaly on ultrasound/MRI/CT
  - EGD demonstrating esophageal varices
  - Clinical signs and symptoms consistent with substantial or advanced fibrosis or cirrhosis
Practitioners who can prescribe Hep C treatment:

- Gastroenterologist, hepatologist, liver transplant or infectious disease subspecialty **physician**
- If the prescribing provider is **not** one of these identified physicians, then prescriber must submit:
  - documentation of consultation/collaboration of the specific case with one of the aforementioned specialists
  - must reflect discussion of the patient’s history with the specialty physician and that physician’s agreement with the plan of care
  - date of discussion and signature of specialist in the progress notes
Current Covered DAA Medications:

**Daklinza™** (daclatasvir) - genotypes 1 or 3 in combination with sofosbuvir

**Epclusa®** (sofosbuvir/velpatasvir) - genotypes 1, 2, 3, 4, 5, or 6 with or without ribavirin

**Harvoni™** (ledipasvir/sofosbuvir) – genotypes 1, 4, 5, or 6 with or without ribavirin

**Mavyret™** (glecaprevir/pibrentasvir) – genotypes 1, 2, 3, 4, 5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A). Also indicated for genotype 1 previously treated with regimens containing either an NS5A inhibitor or an NS3/4A PI but not both.

**Olysio®** (simeprevir) - genotype 1 or 4 as a component of a combination regimen

**Sovaldi®** (sofosbuvir) - genotype 1, 2, 3, or 4 as a component of a combination regimen
Technivie™ (ombitasvir/paritaprevir/ritonavir) – genotype 4 (without cirrhosis) in combination with ribavirin

Viekira PAK™, Viekira XR™ (ombitasvir/paritaprevir/ritonavir/dasabuvir) - genotype 1 with or without ribavirin including in those with compensated cirrhosis.

Vosevi™ (sofofuvir/velpatasvir/voxilaprevir) – genotypes 1, 2, 3, 4, 5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A) and previously treatment with an NS5A inhibitor or have genotype 1a or 3 and previously treated with sofosbuvir without an NS5A inhibitor

Zepatier™ (elbasvir/grazoprevir) - genotype 1 or 4 with or without ribavirin
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<thead>
<tr>
<th>Medication</th>
<th>Number of approvals (as of June 2018)</th>
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<tbody>
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<td>Daklinza</td>
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<td>Vosevi</td>
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<tr>
<td>Zepatier</td>
<td>193</td>
</tr>
</tbody>
</table>

**Total Approvals** 3674  
**Total Unique Patients** 3415
Hepatitis C Lawsuits

- Since approval of Sovaldi and many states Hep C coverage restrictions, there have been multiple lawsuits to change coverage criteria
- Michigan was also sued and final settlement determinations will be announced in the fall
- Changes to coverage include:
  - Treating F1 patients starting October 2018
  - Treating F0 patients starting October 2019
Future Collaborations:

- Working with Population Health to:
  - Improve surveillance of Hep C treatment outcomes
  - Monitor for patient’s with positive Hepatitis C testing but no apparent treatment
Questions?