Hepatitis C Treatment Access

Barbra Cave, MSN, APN, FNP-BC
University of Louisville
July 26, 2017

LOUISVILLE.EDU

Disclosures

Speaker's Bureau
Gilead
Janssen
AbbVie
Merck
Bristol-Myers-Squibb

Advisory Boards
Gilead
AbbVie
Bristol-Myers-Squibb

There will be no promotion of specific Hepatitis C Medications in this presentation.

LOUISVILLE.EDU

Outline

Insurance Requirements
Commercial
Medicaid
Medicare
Uninsured

Advocacy
Appeals and Peer-to-Peer
Role of Specialty Pharmacies

Assistance Programs
Drug Vendors
Foundations
Philanthropy

Case Studies
Insurance Requirements

Moving Targets with Multiple Factors to Consider

- Plan Formulary
- Patient Readiness
  - Socially
  - Emotionally
  - Medically
- Length of Sobriety/engagement in treatment
- Degree of Fibrosis
- Extrahepatic Complications of Hepatitis C

Pharmaceutical assistance programs may be able to cover the cost of medication.

These plans do not typically cover the cost of:
- Specialty Office Visits
- Labs
- Medical Imaging

KYNECT!
### Plan Formulary Highlights

Based on Genotype, past treatment, resistance testing

<table>
<thead>
<tr>
<th>Plan</th>
<th>Passport: 279,016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aetna (formerly Coventry)</td>
<td>270,958</td>
</tr>
<tr>
<td>Wellcare</td>
<td>432,571</td>
</tr>
<tr>
<td>Humana CareSource</td>
<td>95,022</td>
</tr>
<tr>
<td>Anthem Medicaid</td>
<td>5,000</td>
</tr>
<tr>
<td>Total Medicaid in Kentucky as of March 2016:</td>
<td>1,327,495 (in FY 2010: 788,242)</td>
</tr>
</tbody>
</table>

- Anthem: 385,080
- Humana: 139,236
- United Healthcare: 13,112
- Bluegrass Family Health: 40,080
- Aetna: 3,064

**Total Commercially insured in Kentucky based on 2009 data:** 580,572

- Anthem: 385,080
- Humana: 139,236
- United Healthcare: 13,112
- Bluegrass Family Health: 40,080
- Aetna: 3,064

### Patient Readiness

**History, History, History!**

**Plan Abuse**

**Passport**

- 30% sobriety
- AUDIT
- CAGE

**Aetna (formerly Coventry)**

- 1 UDS/ETOH

**CareSource**

- 3 UDS/ETOH
- 60 days apart

**Wellcare**

- 2 UDS/ETOH

**Medicare**

- If history of significant past use/abuse, documentation of treatment program is needed

**Humana**

- Not actively using

**Cigna**

- 6 months sobriety

**United Healthcare**

- 6 months sobriety
- 6 months sobriety
- Viral load x2 6 months apart

### Socially, Emotionally

- Stable Housing?
- Working?
- Transportation?
- Reading ability?
- Insurance changing soon?
- Parole?
- Sandwich?
- Depressed?
- Psych History?

*Image taken from 'http://www.farrlawfirm.com/sandwich-generation/its-not-just-the-sandwich-generation-its-a-triple-decker/ on 5.5.16*
Patient Readiness

Medical Status
- Medication Compliance
- Diabetes Control
- Co-morbidities
- Co-infections
- Cancer Treatment
- Planned surgery and recovery time
- Past Hep CTreatment - when, with what, what response?

Patient Readiness

Liver Assessment
- Liver ultrasound or CT
- Fibrosis Assessment (Fibroscan, Fibrosure, Fibrotest, APRI, FIB4, liver biopsy)
- Genotype, viral load
- CBC, CMP, PT/INR
- Hepatitis A and B immunity/infection status, HIV status
- If needed: AFP/AFPP-L3, Urine drug screen, ETOH screen, ceruloplasmin, AMA, ASMA, ferritin, alpha-1 antitrypsin, HFE, NSSA drug resistance profile, etc.

It takes a lot of work!
Are you ready for this?
The Work-Up is Complete! Time to Prescribe!

Advocacy = Approvals

Patients need help navigating the system
Nurse Connectors, Insurance Plans, Prescribers, Drug Manufacturers, Insurance Commissions, Advocacy Groups, Specialty Pharmacies
Tracking is Key

- Automated systems
- Review staff may not be medically savvy
- (fatty liver vs. steatosis vs. steatohepatitis vs. NASH)
- Data "too old"
- Missing data

Remember- the fax may confirm transmission, but it does not guarantee it was received!
Appeals and Peer-to-Peer Reviews

- Can take as little as a few minutes or up to 30 days to process
  - Expedited Review vs. Standard Review
- Provides a forum for the prescriber/patient to state their case
  - For Peer-to-Peer reviews, a phone call to arrange an "appointment" is often required
- For Medicare/Medicaid patients:
  - Written or Verbal permission from the patient is required when the provider is submitting the appeal
- For Commercially insured patients:
  - Most payers allow for direct submission from the provider

Kentucky Insurance Commission

Templates!

Appeal Letters Made Easy!

An appeal letter is required for the treatment of Your Member with 12 weeks of Hepatitis C Treatment. Here are the details:

- **DOB:** 7/25/1955
- **Member ID:** 123A45678
- **Medication:** HEPATITIS C TREATMENT

**Dear Reviewer,**

I am writing to support my request for the treatment of Your Member with 12 weeks of Hepatitis C Treatment. Your Member has genotype 1 chronic hepatitis C (B18.2) with a fibrosis score of F3 based in Fibroscan and Fibrosure testing completed last month. Your Member's medical problems also include Chronic Kidney Disease stage 4, which precludes the use of your preferred formulary treatment. His viral load was 7,891,012 as of 6/1/2016, and his drug and alcohol screens were negative.

Supporting documentation is attached for your review. In light of this information, I kindly request prompt approval of Hepatitis C Treatment for Your Member. I can be reached by phone at (502) 999-9999 should you have any questions.

Regards,

Barbra Cave, APRN
Hepatology
Appeal Letter Submission Tips

- Keep it to 1 page
- Counter the denial reason
- Provide missing data
- Be concise
- Consider having patients sign an "Appeals Permission Letter" ahead of time
- "Front Load" the order of documents

Insurance Company
July 15, 2016
To Whom It May Concern,
Barbra Cave, APRN has permission to file an appeal on my behalf. Please review her letter, notes, and any supporting documentation in light of the request for Hepatitis C Treatment. I can be reached at the phone number below if needed.

Barbra Cave
502-999-9999
Member ID: 123456789

Specialty Pharmacy

Assistance Programs

- Benefits Investigation
- Securing copay cards/grants
- Patient Education
- Drug-Drug interaction double-check
- Medication Reminders
- Refill Reminders
- Prior Authorization
- Appeals
- Canary in a mine...

Image taken from http://www.petergrandich.com/is-copper-really-a-canary-in-a-coal-mine/ on 5.5.16
Pharmaceutical Company Support

Company & Program Information

AbbVie - ProCeed Support Program
www.viekira.com/proceed-support 844-277-6233

Bristol-Myers Squibb - Patient Support Connect
https://bmsdm.secure.force.com/patientsupportconnect/patient 844-442-6663

Genentech - Genentech Access Program
www.genentech-access.com/pegasys/patients 888-941-3331

Gilead - Support Path

Janssen - Access One
www.olysio.com 855-565-9746

Kadmon
www.ribapak.com 877-377-7862

Merck - Merck Access Program
www.merckaccessprogram-zepatier.com/hcc 866-251-6013

Pharmaceutical Company Support

Patient Advocacy Foundations

Hepatitis C Advocate
www.hepadvocate.org

Patient Advocate Foundations Hepatitis C line
www.hepatitis.patientline.org 800-532-5274

Patient Access Network Foundation
www.PANfoundation.org 888-316-7263

Partnership for Prescription Assistance
www.pparx.org 888-477-2669
Case Studies: Highlighting How Advocacy Works!

The case of JG

Treatment naïve, diagnosed with cirrhosis in 2010. On hemodialysis since 2009. Co-morbidities include HTN, dyslipidemia, chronic pancreatitis, CKD, gastroparesis, and left eye blindness.

Medications: Albuterol, amlodipine, docusate, Fosrenal, Humulin, Hydralazine, Keytruda, minocycline, gabapentin, oxycodone, promethazine, Risperdal, Zofran

Seen 12/15/15, rx written 2/16/16 (JG was slow to get needed labs). PA denied in late February due to non-formulary request. New rx written for preferred medication on 4/4/16. It was Denied. In review of prescription tracking, it was determined many patients with this patient’s plan were being denied who clearly met criteria. After contacting lead pharmacist at the plan, it was determined JG met criteria and the PBM had denied her in error. She was approved on 4/27/16.
The case of DE


Exam done 11/20/15, 12/22/15, and 1/29/16. Rx written 2/15/16. She was too decompensated in Nov and Dec to treat, but we started collecting her required UDS/ETOH screens. By February, she was stable enough to proceed with treatment. PA denied and appeal sent in 3/4/16. On 4/27/16 received notice from Heme/Onc she is developing signs of lymphoma. Discovered appeal from 3/4/16 was “never received” so Expedited appeal letter was sent on 6/23/16. On 5/5/16, a call was placed to see what the outcome of the Expedited Appeal was... We’re sorry, it was sent to the regular appeals route. We will have a decision tomorrow.” On 5/10/16, a Clinical Pharmacist returned our call to do a Peer-to-Peer. He stated they were missing proof of negative ETOH screens and cirrhosis. The records were all there, they simply needed to be pointed out... she was finally approved.

The case of JR

32 y/o, treatment Naïve G2B, F1 with Bipolar d/o and h/o IVDA-Athenn

Diagnosed with HCV in 2015 following IVDA and subsequent drug rehab program. Co-morbidities include Anxiety disorder and asthma. Medications: Albuterol, Naltrexone, Neurontin, Wellbutrin, Klonopin.

Exam done 9/11/15, re sent on 9/29/15. Denied by Anthem. Appeal denied 10/23/15. Effective 1/1/16, Anthem removed fibrosis requirements. New re sent to Anthem on 1/15/16, denied for unclear reasons. New exam/labs done 3/4/16. Rx re-submitted and approved on 4/6/16. Medications were delivered, but she was having an anxiety episode and worried about using drugs/drinking ETOH because she had lost her job and was facing homelessness. She was referred back to her Psychiatric provider for treatment. As of 5/5/16, she had not started treatment yet.

The case of CT

25 y/o with F0 disease- United Healthcare

Diagnosed with G1A in 2014 following completion of drug rehab program at the Healing Place in 2013. CT had used Heroin about 1 year and had abused alcohol for about 5 years. Co-morbidities: none. Medications: none.

He was seen in January 2015 and denied treatment. He was lost to follow-up for several months. He returned 9/22/15 and found to have F1 disease. Rx written 9/22/15, denied. Appeal sent in October; denied. Effective 1/1/16, United Healthcare changed guidelines and removed Fibrosis requirements. He was seen 2/5/16 for exam and updated labs. Approved and started treatment 3/28/16.
The case of DT

60 y/o WM retired from Ford (Anthem is the benefits administrator)
Co-morbidities include smoking, obesity, HTN, dyslipidemia, and arthritis
Medications: Lisinopril, amlodipine, pravastatin, ibuprofen, multivitamin, milk thistle, glucosamine chondroitin
Fibrosis stage 3

Seen in clinic 11/10/15, rx written 11/24/15. Rx denied- "not covered" by plan. Appeal sent to plan but denied in December. Advised DT to call his Union Representative to help appeal for coverage- this was successful. DT started treatment 1/18/16 and finished therapy 8 weeks later.

G1A, F3, treatment naïve and a self-funded plan

Thank you for your attention!

Special Thanks:
Jewish Hospital Transplant Center/Hepatitis C Treatment Clinic
Erica Rose, RN
Leah Conant, LPN

University of Louisville Division of Gastroenterology
Lillie Hutchinson, CRNA
Joni Willard, PA
Carla Siler, PA
Adrienne Marcum, MD

Pharmacy Plus Specialty Pharmacy
Laura Hicks, PharmD
Kathy Anderson, PharmD
Laura Smart, MD * Medical Director for Hep C Clinic
Joel Wiseman, PharmD

Lillie Hutchinson, CMA
Matt Cave, MD
Kathy Anderson, PharmD
Craig McClain, MD

Special thanks to those working hard to treat patients and link them to care:
Mary Bishop, PharmD; Pharmacist with University of Louisville
Kathy Sanders, RN; Kentucky State Viral Hepatitis Coordinator
Sarah Mayer, MD; Louisville Metro Department of Public Health and Wellness