


Hepatitis C Treatment Access

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University of Louisville
July 26, 2017



Disclosures

Speaker's Bureaus


- 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.

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Outline



Insurance Requirements

- Commercial
- Medicaid
- Medicare
- Uninsured

Advocacy

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

Assistance Programs

- Drug Manufacturers
- Foundations
- Philanthropy

Case Studies

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Insurance Requirements

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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

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What about the Uninsured?

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!

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Plan Formulary Highlights

Based on Genotype, past treatment, resistance testing

30% {

- Passport: 279,016
- Aetna (formerly Coventry): 270,958
- Wellcare: 432,571
- Humana CareSource: 120,328
- Anthem Medicaid: 95,552

Total Medicaid in Kentucky as of March 2016:
1,327,495 (in FY 2010: 788,242)

- 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

Medicare: 862,887 as of 2015

Kentucky Total Population as of 7/1/15: 4,425,092. In 2010: 4,339,367

Sources: Kentucky Cabinet for Health and Family Services, Department of Medicaid Services Monthly Membership Counts taken 5.5.16
Community and Economic Development Initiative of Kentucky: 2012 Kentucky Healthcare Market Report taken 5.5.16
US Census data taken 5.5.16

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Patient Readiness

History, History, History!

Plan	Abuse history	Alcohol	Special Requirements
Passport	6 months sobriety	AUDIT-C or CAGE	1 UDS/ETOH
Aetna (Coventry)			1 UDS/ETOH
CareSource			3 UDS/ETOH 30 days apart
Wellcare			1 UDS/ETOH
Medicare			
Anthem	Not actively using		If history of significant past use/abuse, documentation of treatment program is needed
Humana			
Cigna			
United Healthcare	6 months sobriety	6 months sobriety	Viral load x2 6 months apart

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Patient Readiness

Socially, Emotionally

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



Image taken from <http://www.fairfaxfilm.com/sandwich-generation/its-not-just-the-sandwich-generation-its-a-triple-decker/> on 5.5.16

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Patient Readiness

Medical Status

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

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Patient Readiness

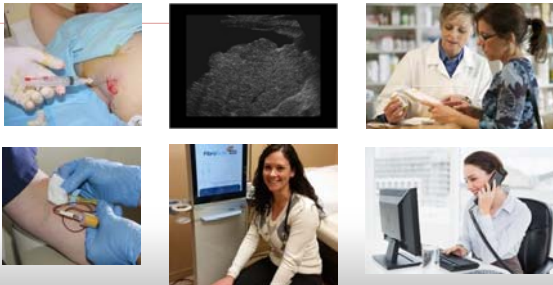
Liver Assessment

- Liver ultrasound or CT
- Fibrosis Assessment (Fibroscan, Fibrosure, Fibrotest, APRI, FIB4, liver biopsy)
- Genotype, viral load
- CBC, CMP, Pv/INR
- Hepatitis A and B immunity/infection status, HIV status
- If needed: AFP/AFP-L3, Urine drug screen, ETOH screen, ceruloplasmin, AMA, ASMA, ferritin, alpha-1 antitrypsin, HFE, NS5A drug resistance profile, etc.

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It takes a lot of work!

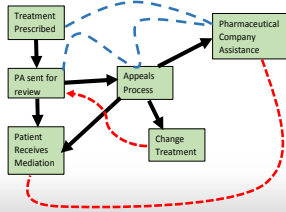


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The Work-Up is Complete! Time to Prescribe!

Are you ready for this?



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Advocacy = Approvals

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Patients need help navigating the system



dreamstime

Nurse Connectors, Insurance Plans, Prescribers, Drug Manufacturers, Insurance Commissions, Advocacy Groups, Specialty Pharmacies

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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

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Kentucky Insurance Commission



Appealing a Denial From Your Health Benefit Plan - A How-To Guide

Your member deserves a chance at coverage. What can you do?

Consider your rights under the federal Health Care Reform law, the Affordable Care Act, as well as the right to appeal with a health insurance issuer.

What exactly is an appeal?

An appeal is a request to a decision maker for a health care, treatment, drug or service.

- For health plans
- Covered organizations
- Health care providers
- Health care plans
- Health care services

How does an appeal work?

Appeals to health plans are for the purpose of requesting the health plan to reconsider its decision to deny or limit coverage. Appeals to health care providers are for the purpose of requesting the provider to reconsider its decision to deny or limit coverage. Appeals to health care services are for the purpose of requesting the health plan to reconsider its decision to deny or limit coverage.

What is the process for appealing an appeal?

If you are appealing a denial, you should first contact the health plan to request a reconsideration. If you are appealing a denial from a health care provider, you should first contact the provider to request a reconsideration. If you are appealing a denial from a health care service, you should first contact the health plan to request a reconsideration.

What is the process for appealing an appeal?

If you are appealing a denial, you should first contact the health plan to request a reconsideration. If you are appealing a denial from a health care provider, you should first contact the provider to request a reconsideration. If you are appealing a denial from a health care service, you should first contact the health plan to request a reconsideration.

Source: http://insurance.ky.gov/news/pubs.aspx?Div_id=4465

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Appeal Letters Made Easy!

Templates!

Insurance Company
Attn: Appeals
Fax: 888-999-9999
July 26, 2016

Re: Your Member
DOB: 7/25/1985
Member ID: 12345678
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 (B14.2) with a fibrosis score of F3 based on Fibroscan and Fibrotest 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,

Barbara Cave, APRN
Hepatology

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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 26, 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 she might send in to support the request for my Request C Treatment. I can be reached at the phone number below if needed.

Thank you,

Your Patient
 502-999-9999
 Member ID: 1234446789

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Specialty Pharmacy

Assistance and Assistants

- 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.petergendich.com/fr-copper-really-a-canary-in-a-coal-mine/> on 5.5.16

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Assistance Programs

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Pharmaceutical Company Support

Services Offered

- Copay Assistance
- Specialty Pharmacy Locator
- Benefits Verification
- HCV Provider Locator
- Care Counselors/Nurses
- Patient Education
- Medication Reminders
- Phone
- Computer
- In-Person

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Pharmaceutical Company Support

Company & Program Information

- [AbbVie- ProCeed Support Program](http://www.viekira.com/proceed-support)
www.viekira.com/proceed-support 844-277-6233
- [Bristol-Myers Squibb- Patient Support Connect](https://bmsdm.secure.force.com/patientsupportconnect/patient)
https://bmsdm.secure.force.com/patientsupportconnect/patient 844-442-6663
- [Genentech- Genentech Access Program](http://www.genentech-access.com/pegasys/patients)
www.genentech-access.com/pegasys/patients 888-941-3331
- [Gilead- Support Path](http://www.MySupportPath.com)
www.MySupportPath.com 855-769-7284
- [Janssen- Access One](http://www.olyrio.com)
www.olyrio.com 855-565-9746
- [Kadmon](http://www.ribapak.com)
www.ribapak.com 877-377-7862
- [Merck- Merck Access Program](http://www.merckaccessprogram-zepatier.com/hcc)
www.merckaccessprogram-zepatier.com/hcc 866-251-6013

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Patient Advocacy Foundations

- **Clinical Trials**
- **Education**
- **Appeals Assistance**
- **Linkage to Care**
- **Treatment Funding**
- Hepatitis C Advocate**
www.hepcadvocate.org
- Patient Advocate Foundations Hepatitis C line**
www.hepatitisc.patcareline.org 800-532-5274
- Patient Access Network Foundation**
www.PANfoundation.org 866-316-7263
- Partnership for Prescription Assistance**
www.pparx.org 888-477-2669

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UL Philanthropy

Raising Global Awareness

phil · lan · thro · pist

Advocacy
 Case and name in case effort to promote nurse without
 the name of the disease

The Hepatitis C Trust (United Kingdom)
<http://www.hepctrust.org.uk/>

American Liver Foundation
<http://www.liverfoundation.org/>

Hepatitis Foundation International
<http://www.hepatitisfoundation.org/>

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Case Studies: Highlighting How Advocacy Works!

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UL 56 y/o AAF with cirrhosis and ESRD on hemodialysis- Passport

The case of JG

Treatment naive, diagnosed with cirrhosis in 2010. On hemodialysis since 2009. Co-morbidities include HTN, dyslipidemia, chronic pancreatitis, DM2, gastroparesis, and left eye blindness.
 Medications: Albuterol, amlodipine, docusate, Fosrenal, Humulin, Hydralazine, Kayexalate, minoxidil, 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.

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62 y/o with decompensated cirrhosis- Caresource

The case of DE

Treatment naïve, diagnosed with cirrhosis in 2014. Cirrhosis is complicated by hepatic encephalopathy.

Exams: usually unremarkable except for slowed speech and appearing fatigued.

Co-morbidities: chronic pain, hyperlipidemia, HTN, MRSA of skin

Current medications: Lactulose, Lexapro, Lisinopril, Methadone, Neurontin, Pravastatin, Seroquel

Seen 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 4/27/16. 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!

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

The case of JR

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, rx sent in on 9/29/15. Denied by Anthem. Appeal denied 10/23/15.

Effective 1/1/16, Anthem removed fibrosis requirements. New rx 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.

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25 y/o with F0 disease- United Healthcare

The case of CT

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.

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

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 1/8/16 and finished therapy 8 weeks later.

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Thank you for your attention!

Special Thanks:

Jewish Hospital Transplant Center/Hepatitis C Treatment Clinic

Erica Rose, RN
Leah Cashion, LPN

Pharmacy Plus Specialty Pharmacy

Roshawn Allen
Lillie Hutchinson, CMA
Kathy Anderson, PharmD
Jim O'Donnell, PharmD
Mark Milburn, PharmD

University of Louisville Division of Gastroenterology

Laura Smart, MD * Medical Director for Hep C Clinic
Matt Cave, MD
Luis Marsano, MD
Craig McClain, MD
Ashutosh Barve, MD

Others 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 Moyer, MD; Louisville Metro Department of Public Health and Wellness

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