

Ohio Department of Medicaid (ODM) P&T Committee Meeting Minutes

April 8, 2015

77 S. High Street, Columbus, OH, Room 1932

Committee members present: Susan Baker, CNS; Suzanne Eastman, PharmD; Mike Howcroft, RPh; Cheryl Huffman, MD; Karen Jacobs, DO, Acting Chair; Melissa Jefferis, MD; Margaret Scott, RPh

Xerox staff present: Stephanie Levine, PharmD, Clinical Manager

ODM staff present: Patti Nussle, RPh; Jill Griffith, PharmD

Approximately 37 stakeholders were present, most representing pharmaceutical manufacturers.

The meeting was called to order at 10:06 AM by Dr. Jacobs, acting chair.

- 1) Conflict of Interest Statement. Committee members who were not present at the January meeting signed the annual conflict of interest statement. P&T Committee members are required to sign the statement annually.
- 2) Interested Party Presentations
 - Brian Beesley, DO, primary care HIV specialist, requested that the Committee add Prezcofix as a preferred drug.
- 3) Old Business
 - a) Dr. Levine presented information on ODM fee-for-service utilization of drugs for hepatitis C virus (HCV) treatment through February 2015. The presentation is attached to these minutes.
 - b) Preferred Drug List (PDL) changes to be discussed at June P&T meeting
 - i) Ms. Scott presented information about new Ohio Administrative Code rule 4731-11-12, Office based opioid treatment, and compared current ODM prior authorization criteria to the new Medical Board standards. A copy of the presentation is attached to these minutes.

Dr. Jacobs suggested that ODM should send the new guidelines to all buprenorphine providers, and possibly do random prescriber audits.

Dr. Jacobs suggested an immediate change to a maximum dose of buprenorphine of 16mg per day. The vote was unanimous. Other changes to the PA criteria will be discussed at the next meeting.
 - ii) Ms. Scott presented the new drug classes to be added to the PDL, details attached to these minutes:
 - (1) Analgesics – Topical NSAIDs
 - (2) Gastrointestinal – Chronic Constipation: Opioid-Induced Constipation
 - (3) Immunomodulators – Oral Immunosuppressants
 - (4) Infectious Disease – Inhaled Antibiotics
 - (5) Respiratory – Hereditary Angioedema
- 4) New Business: Drugs Under Review
 - a) Blood Agents: Oral Anticoagulants. Savaysa (edoxaban) tablets, Daiichi-Sankyo

A representative from Daiichi-Sankyo presented clinical information. Dr. Jacobs noted the indication requires 5-10 days of parenteral anticoagulation for venous thromboembolism and asked if the manufacturer has completed any head-to-head studies with Xarelto. The manufacturer's representative indicated they have not. Dr. Levine presented the ODM and Xerox recommendation for non-preferred status. Dr. Eastman asked what the PA criteria would be for this product; Ms. Scott responded that a patient would need a trial on a preferred agent (warfarin or Xarelto) for 14 days. The vote for non-preferred status was unanimous.

- b) Endocrine: Oral Hypoglycemics. Jardiance (empgliclozin) tablets, Boehringer Ingelheim
A representative from Boehringer Ingelheim presented clinical information. Dr. Levine presented the ODM and Xerox recommendation for non-preferred status. Dr. Jacobs asked about the PA criteria; Ms. Scott responded that all of the selective sodium-glucose transporter-2 (SGLT2) inhibitors are on tier three of the PDL. The vote for non-preferred status was unanimous.
- c) Genitourinary Agents: Electrolyte Depletor Agents. Auryxia (ferric citrate) tablets, Keryx Biopharmaceuticals
A representative from Keryx presented clinical information. Dr. Levine presented the ODM and Xerox recommendation for non-preferred status. Dr. Jacobs asked about the PA criteria; Ms. Scott responded that the recommendation is for tier three. The vote for non-preferred status was unanimous.
- d) Infectious Disease Agents: Antivirals – Hepatitis C. Viekira Pak (ombitasvir/paritaprevir and ritonavir tablets; dasabuvir) tablets, Abbvie
A representative from Abbvie presented clinical information. Mr. Howcroft gave additional information regarding questions the committee members asked at the January meeting. First, the committee members had asked about the definition of decompensated cirrhosis. Mr. Howcroft found that a Child-Turcotte-Pugh score of 7 and above is decompensated cirrhosis, while a score of 6 or below is the liver can compensate. The committee had also asked whether the recommendation is to complete the hepatitis B vaccination series prior to beginning treatment for HCV; Mr. Howcroft said that this is the recommendation. Ms. Scott reminded the committee of the criteria they had approved at the January meeting, and gave the recommendation that Viekira Pak be included in these criteria. ODM also recommends that if a regimen exists that is recommended by the American Association for the Study of Liver Diseases / Infectious Diseases Society of America (AASLD/IDSA) guidelines that does not include Sovaldi, and instead includes Harvoni or Viekira Pak, that the Sovaldi-containing regimen be non-preferred. The committee vote for these recommendations was unanimous.
- e) Infectious Disease Agents: Antivirals – HIV.
(1) Evotaz (atazanavir/cobicistat) tablets, Bristol-Myers Squibb
(2) Prezcoibix (darunavir/cobicistat) tablets, Janssen
Representatives from Bristol-Myers Squibb and Janssen presented clinical information. Ms. Scott discussed that these products are combinations of existing, single-ingredient products that are preferred on the PDL with a booster agent, cobicistat. Most patients who take the single-ingredient products use Norvir (ritonavir) as a boosting agent, so these combination products may reduce the daily pill burden by one. Ms. Scott also explained that changes to the federal rebate program as part of the Affordable Care Act have not been clarified so ODM is unable to determine the expected rebates from these

products. Ms. Scott said the recommendation from ODM and Xerox for these products is non-preferred. The committee vote was unanimous.

f) Respiratory Agents: Long-Acting Beta Agonists (LABA). Striverdi Respimat (olodaterol inhalation spray), Boehringer Ingelheim

A representative from Boehringer Ingelheim presented clinical information. Ms. Scott reminded the committee of the criteria for all LABAs, step therapy after inhaled anticholinergics or steroids, and recommended non-preferred status that also requires a two-week trial on a preferred product, currently Foradil. Dr. Eastman said that this product is superior to the current preferred product, because it is once-daily dosing, and the device is easier than Foradil or Arcapta; for older patients, the delivery device is important. Dr. Jacobs asked the committee members whether a two-week trial on a preferred product is appropriate. Dr. Jefferis said that it is uncertain whether a patient would be likely to have an exacerbation within two weeks, but noted that most patients with COPD have many comorbidities. The committee vote was 5 to 1 in favor of preferred status, with Ms. Scott dissenting.

The meeting was adjourned at 11:53 AM with a reminder that the next meeting is scheduled for Wednesday, June 10, 2015, beginning at 9:00 AM.



Ohio | Department of Medicaid
 John R. Kasich, Governor
 John B. McCarthy, Director

Pharmacy and Therapeutics Committee
 April 8, 2015
 Stephanie Levine, PharmD

Department of Medicaid

4Q2014 vs 3Q2014 OHIO DEPARTMENT of MEDICAID FEE FOR SERVICE (ODM-FFS) HEPATITIS C VIRUS (HCV) PRESCRIPTIONS AND DRUG SPEND

Drug	4Q2014			3Q2014		
	# Claims	Total Amount Paid to Pharmacies	% of Total Amount Paid to Pharmacies	# Claims	Total Amount Paid to Pharmacies	% of Total Amount Paid to Pharmacies
SOVALDI	57	\$1,648,959	79%	92	\$2,636,480	67%
RIBAVIRIN	51	\$15,085	1%	63	\$19,203	0%
OLYSIO	18	\$402,392	19%	51	\$1,159,787	29%
PEGYLATED INTERFERON	7	\$19,345	1%	26	\$91,628	2%
TOTALS	133	\$2,088,536	100%	232	\$3,907,098	100%

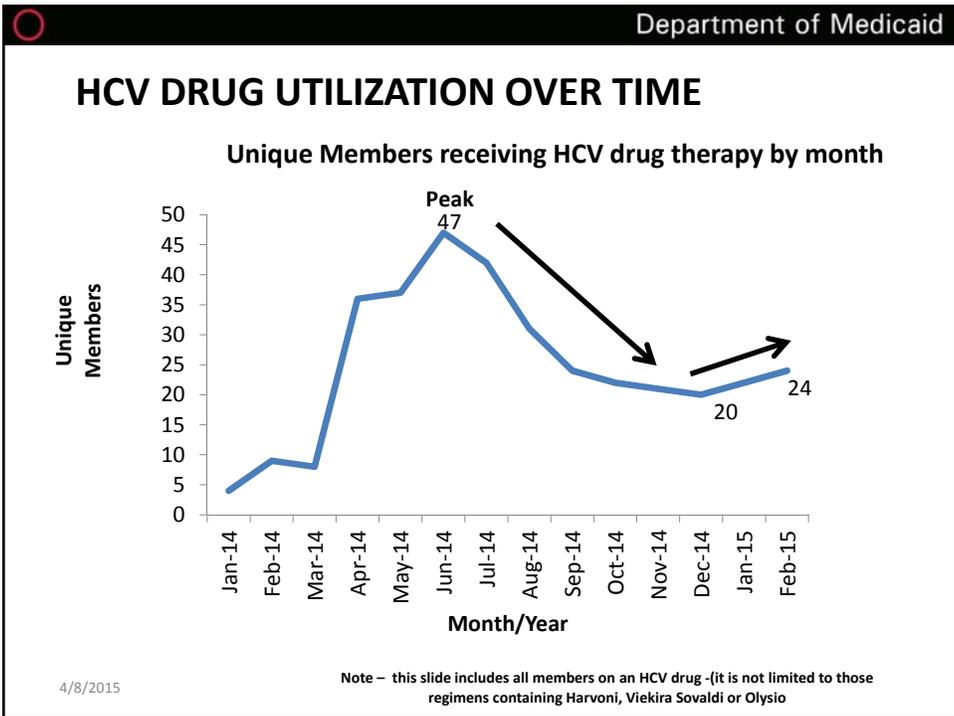
Note(s):

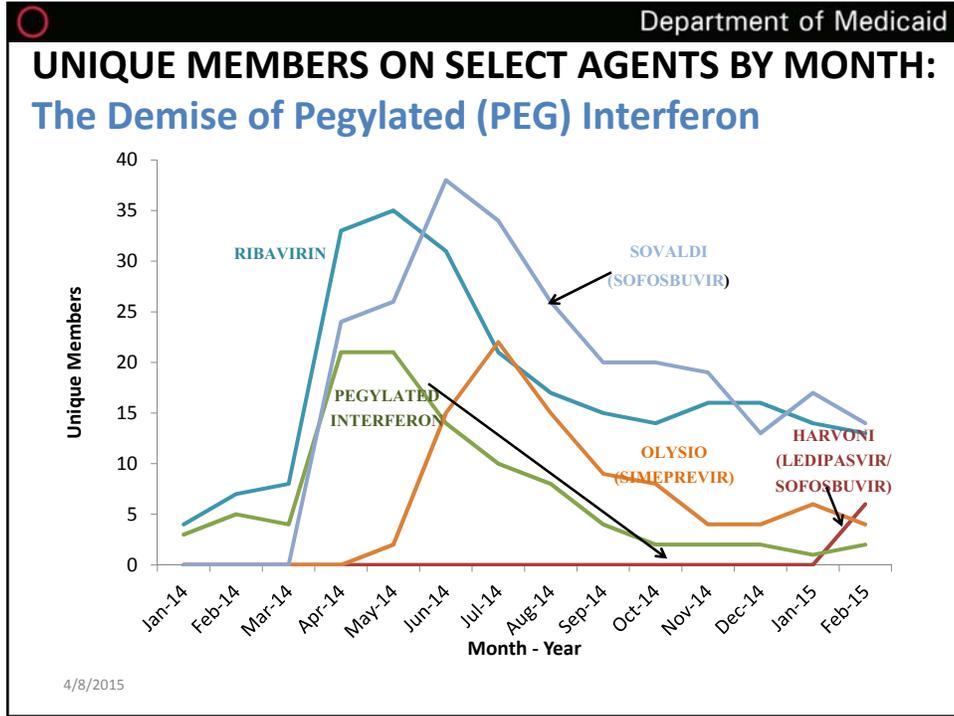
- Ribavirin includes all formulations, brand and generic
- Pegylated Interferon includes Pegasys and Peg-Intron
- Unless otherwise noted, from this slide going forward, all data is inclusive only of those drug regimens that contain any one or a combination of Olysio, Sovaldi, Harvoni or Viekira

Department of Medicaid

JAN 2014 - FEB 2015: UNIQUE MEMBERS and TOTAL PRESCRIPTIONS

DRUG NAME	Unique Members	Total RX	Unique Members	Total RX
	Jan 14-Feb 15	Jan 14 -Feb 15	Jan 14-Jan 15	Jan 14 -Jan 15
SOVALDI	121	274	119	260
RIBAVIRIN	106	276	104	261
PEGYLATED INTERFERON	49	117	49	115
OLYSIO	40	100	40	96
HARVONI	6	6	0	0
TOTALS	n/a	773	n/a	732





Department of Medicaid

CLINICAL NEWS

DRUG NAME	MFT	COMMENTS
grazoprevir/ elbasvir	Merck	February 2015: FDA notifies both manufacturers of its <i>intention</i> to rescind the break through therapy designation of each drug due to existing approved HCV therapy. If the designation is officially rescinded, the FDA review date and potential approval of both agents will be later than initially anticipated (standard approximate ten months after NDA filing). Neither manufacturer has filed an NDA; however, both are anticipated to do so in the first half of 2015.
daclatasvir	BMS	
Sovaldi	Gilead	March 2015: The FDA approved an update to the label warning of serious symptomatic bradycardia when the drugs are coadministered with amiodarone. Gilead reported at least nine reported cases of bradycardia, including one fatal heart attack and three of the patients requiring pacemakers were linked to the concurrent use of the agents.
Harvoni		

Department of Medicaid

MARKET EVENTS -ENHANCED HCV DRUG COMPETITION

State Medicaid FFS Coverage of Harvoni, Viekira, Sovaldi and Olysio as of March 30, 2015

Medicaid FFS	Preferred HCV Agent (s)
MOHealthNet	Viekira only
Minnesota	Viekira only
North Carolina	Viekira only
District of Columbia	Viekira only
Georgia	Viekira, Harvoni, Sovaldi
Indiana	Viekira, Harvoni, Olysio

Medicaid FFS	Preferred HCV Agent (s)
Kentucky	Sovaldi
Maryland	Sovaldi
Pennsylvania	Olysio, Sovaldi

Note: Different States have different guidelines on the posting of non-preferred and non-reviewed drugs; hence, only posted preferred agents are noted. States also have varied review schedules and newer agents (ie Harvoni and Viekira) may not have been reviewed yet in all States noted above.

4/8/2015

Department of Medicaid

HCV DRUG REGIMENS UTILIZED

HCV REGIMEN	JAN 2014 - FEB 2015		JAN 2014- OCT 2014	
	# Unique Members	% of all Regimens	# Unique Members	% of all Regimens
RIBAVIRIN/SOVALDI	48	38%	37	37%
OLYSIO/SOVALDI	39	31%	33	33%
PEGYLATED INTERFERON/ RIBAVIRIN/SOVALDI	31	25%	29	29%
HARVONI	6	5%	0	0%
RIBAVIRIN/OLYSIO/SOVALDI	1	1%	1	1%
SOVALDI* (TPL member)	1	1%	0	0%
Totals	126	100%	100	100%

*

4/8/2015

Department of Medicaid

PRESCRIBERS OF HCV DRUG REGIMENS*

PRESCRIBER SPECIALTY 1/1/2014 –2/28/2015		
Prescriber Specialty	SubTotal	%
GI	60	47%
Hepatologist	42	33%
ID	21	16%
unknown	5	4%
Grand Total	128	100%

GI: Gastroenterologist
ID: Infectious Disease

4/8/2015

Department of Medicaid

GENOTYPE PREVALENCE

GENOTYPE PREVALENCE – 1/1/2014 –2/28/2015		
Genotype	# Members	%
1	78	60%
1	54	42%
1A	15	12%
1B	9	7%
2	20	15%
2	11	8%
2A/2C*	1	1%
2B	8	6%
3	20	15%
3	16	12%
3A	4	3%
4	3	2%
n/a	9	7%
Grand Total	130	100%

Only those members with a prior authorizations were reviewed.
* The member may have both genotypes (co-infection with multiple genotypes may exist) or the lab testing done on the member was not able to discern between the two subtypes

4/8/2015

CONCLUSION

- Demise of Pegylated interferon is rapidly approaching due to oral alternatives with increased cure rate
- Shift in regimens
- Appropriate therapy management and monitoring
- HCV class will continue to be monitored closely by Ohio Department of Medicaid and Xerox

4/8/2015



Buprenorphine Dosing: Ohio Administrative Code Caps at 16mg/day

P&T Committee April 8, 2015



FDA-Approved Labeling

- Dosing: Administered sublingually as a single daily dose.
 - ✓ The recommended target dosage of SUBOXONE sublingual film is 16 mg/4 mg buprenorphine/naloxone/day
 - ✓ One ZUBSOLV 5.7/1.4 mg sublingual tablet provides equivalent buprenorphine exposure to one SUBOXONE 8/2 mg sublingual tablet. The recommended target dosage of ZUBSOLV sublingual tablet is 11.4 mg/2.8 mg buprenorphine/naloxone/day (two 5.7/1.4 mg tablets)
 - ✓ A BUNAVAIL 4.2/0.7 mg buccal film provides equivalent buprenorphine exposure to a SUBOXONE 8/2 mg sublingual tablet. The recommended daily dose for maintenance is 8.4 mg/1.4 mg.

2

Medical Board: Maximum 16 mg/day

Ohio Administrative Code Rule 4731-11-12, "Office Based Opioid Treatment" effective 1/31/15

Paragraph (B)(10) "The physician shall not prescribe, personally furnish, or administer greater than 16 milligrams of buprenorphine per day to a patient, except in one of the following situations:

"(a) The dosage greater than 16 milligrams was established before the effective date of this rule;

"(b) The physician is a board certified addictionologist or addiction psychiatrist and has determined that a dosage greater than 16 milligrams is required for the patient, and has documented patient specific reasons for the need for a dosage greater than 16 milligrams in the patient's record; or

"(c) The physician has consulted with a board certified addictionologist or addiction psychiatrist who has recommended a dosage greater than 16 milligrams and that fact is documented in the patient's medical record."

3

Medical Board: Maximum 16 mg/day

- Medical board filing: "A panel of five independent experts in addiction medicine was subsequently convened to provide input as to the best current practices in treating opiate addiction...All panel members agreed a prescription above 16 milligrams of specifically approved buprenorphine products per day was not commonly necessary and with a dosage of more that sixteen milligrams per day the patient is more inclined to sell the drug."

4

Most Patients Prescribed \leq 16mg

- Current PDL guideline:
Maximum dose of buprenorphine is 24 mg/day
(16 mg is the target, no patient should receive more than 32 mg/day)
- Medicaid Claims for Suboxone, January 2015:
 - ✓ 546 unique patients
 - **\leq 16mg/day: 467 = 85.5% of patients**
 - ✓ 229 patients (42%) at 16mg/day
 - $>$ 16 mg/day: 79 patients = 14.5% of patients

5

Consensus for 16mg

- FDA-approved product labeling
- Clinical studies
- Pharmacology: the mu-opioid receptors saturated 85% - 92%
- State medical board draft rule
- Medicaid claims data show \leq 16 mg/day is the dose that is filled for 85.5% of patients

6

Department of Medicaid

Current PA Criteria

1. Patient has diagnosis of opioid addiction (NOT approvable for pain)
2. Prescribing physician has a DATA 2000 waiver ID ("X-DEA" number)
3. Patient has been referred counseling for addiction treatment (re-authorizations should indicate how often the patient is receiving counseling)
4. Maximum dose 24mg per day, (16mg is target, no patient should receive more than 32mg)
5. Prescriber has reviewed Ohio Automated Rx Reporting System (OARRS) for opioid prescription use
6. Periodic drug screens are addressed in treatment plan (will be performed by prescriber or by counseling team)
7. For re-authorizations – the dose has been reduced in the previous 6 months, or the patient has been evaluated for a dose reduction and the prescriber and patient agree that a dose reduction would not be beneficial/may be harmful

7

Department of Medicaid

OAC vs. PA Criteria

OAC 4731-11-12 (B)	PA Criteria
Comply with state and federal law	Prescribing physician has a DATA 2000 waiver ID ("X-DEA" number)
Conduct assessment including H&P, mental status, substance use history, appropriate lab tests, pregnancy test, toxicology tests, hepatitis B and C screens	
Practice in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance and tapering	For re-authorizations – the dose has been reduced in the previous 6 months, or the patient has been evaluated for a dose reduction and the prescriber and patient agree that a dose reduction would not be beneficial/may be harmful
Diagnose an opioid disorder using DSM-4 or DSM-5	Patient has diagnosis of opioid addiction (NOT approvable for pain)

8

Department of Medicaid	
OAC vs. PA Criteria	
OAC 4731-11-12 (B)	PA Criteria
Require each patient to actively participate in appropriate behavioral counseling/treatment and document at each visit that the patient is attending <ul style="list-style-type: none"> • Prescriber maintains interactions with counselor • Psychiatrist/addictionologist/addiction psychiatrist may personally provide counseling • If professional treatment complete or patient cannot reasonably be required to obtain, participate in a recovery care program (12-step program) 	Patient has been referred to counseling for addiction treatment (re-authorizations should indicate how often the patient is receiving counseling)
Use a drug product that has been approved by FDA for use in maintenance/detox treatment	PA criteria allow buprenorphine-based products

9

Department of Medicaid	
OAC vs. PA Criteria	
OAC 4731-11-12 (B)	PA Criteria
Prescribing limits: <ul style="list-style-type: none"> • First 12 months, no more than 30 days' supply at a time • First 12 months, personally meet with & evaluate patient monthly and document assessment/plan for continuing treatment • After 12 months, personally meet with & evaluate patient at least every 3 months 	Length of authorizations: 30 days for initial authorization, 6 months for subsequent authorizations
Physician shall not provide to a patient receiving other controlled substances for >12 weeks from any provider, without consultation from addictionologist/addiction psychiatrist	Prescriber has reviewed Ohio Automated Rx Reporting System (OARRS) for opioid prescription use

10

Department of Medicaid	
OAC vs. PA Criteria	
OAC 4731-11-12 (B)	PA Criteria
Physician shall not prescribe >16mg/day, except: <ul style="list-style-type: none"> • Dose >16mg established before 1/31/15 • Physician is addictionologist or addiction psychiatrist and has documented patient-specific reasons • Physician has consulted with addictionologist or addiction psychiatrist who has recommended >16mg and this is documented in medical record 	Maximum dose 24mg per day, (16mg is target, no patient should receive more than 32mg)
Physician shall access OARRS for each patient no less frequently than every 90 days, and document receipt and assessment of report	Prescriber has reviewed Ohio Automated Rx Reporting System (OARRS) for opioid prescription use
11	

Department of Medicaid	
OAC vs. PA Criteria	
OAC 4731-11-12 (B)	PA Criteria
Provide ongoing toxicological testing in compliance with all: <ul style="list-style-type: none"> • Any in-office kit is CLIA-waived • Toxicological testing performed at least monthly for the first 6 months, then randomly at least every 3 months • May accept results of testing performed by treatment program or pursuant to a court order • Screen is failed if inconsistent with treatment plan, physician shall address failed screens in a clinically appropriate manner 	Periodic drug screens are addressed in treatment plan (will be performed by prescriber or by counseling team)
Physician shall complete CME relating to substance use/addiction	
12	

Next Steps

- Review medication assisted treatment products with annual PDL review (June meeting)
- Determine appropriate changes to PA criteria

Analgesic Agents: Topical NSAIDs

LENGTH OF AUTHORIZATIONS: Dependent on medication request

All products in this class require clinical prior authorization:

- Requests for Flector[®] Patch require a diagnosis of acute pain due to minor strains, sprains, and contusions
- Requests for Pennsaid[®] Pump or Solution require a diagnosis of osteoarthritis of the knee(s)
- Requests for Voltaren[®] Gel require a diagnosis of osteoarthritis of the hand(s) or knee(s)
- Approvals for Pennsaid[®] solution and Voltaren[®] gel require history of a 30-day trial each of two different oral NSAIDs within the past 6 months; the approval length will be 3 months with a quantity limit of 1 bottle or tube/month
- Approvals for Flector[®] require history of at least a 7-day trial on one oral NSAID; the approval length will be 14 days with a quantity limit of 2 patches/day

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- If there has been a therapeutic failure to no less than a 14-day trial of at least one preferred medication

TOPICAL NSAIDS

Diclofenac epolamine (Flector[®] Patch)

Diclofenac sodium (Pennsaid[®] Solution, Voltaren[®] Gel)

Gastrointestinal Agents: Chronic Constipation Agents

LENGTH OF AUTHORIZATIONS: 1 year

PDL CRITERIA:

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval

2. The requested medication may be approved if there has been a therapeutic failure to no less than a two-week trial of at least two medications not requiring prior approval

ADDITIONAL INFORMATION

- *Requests for agents for opioid-induced constipation will require a history of 90 days of opioid therapy within the past 3 months*

GASTROINTESTINAL AGENTS: IRRITABLE BOWEL SYNDROME WITH CONSTIPATION AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
POLYETHYLENE GLYCOL (generic of Miralax®) BISACODYL (generic of Dulcolax®) SENNA (generic of Senokot®) CASANTHRANOL/DOCUSATE SODIUM (generic of Peri-Colace®)	AMITIZA® (lubiprostone) LINZESS™ (linaclotide)

GASTROINTESTINAL AGENTS: OPIOID-INDUCED CONSTIPATION AGENTS

Amitiza® (lubiprostone)

Movantik® (naloxegol)

Relistor® (methylnaltrexone bromide)

Immunomodulators: Oral Immunosuppressants

LENGTH OF AUTHORIZATIONS: 6 months

GRANDFATHERING:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (new to Medicaid, samples, etc.), will be approved for PA after prescriber contact.

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- For prevention of transplant rejection, any product may be approved. If the product requested is a brand with generic available, there must be a clinical reason why the generic product cannot be used.

ORAL IMMUNOSUPPRESSANT AGENTS

Azathioprine (Azasan[®], Imuran[®])

Cyclosporine (Gengraf[®], Neoral[®], Sandimmune[®])

Everolimus (Zortress[®])

Mycophenolate mofetil (Cellcept[®])

Mycophenolic acid (Myfortic[®])

Sirolimus (Rapamune[®])

Tacrolimus (Prograf[®], Astagraf XL[™])

Infectious Disease Agents: Antibiotics – Inhaled

LENGTH OF AUTHORIZATIONS: 28 days

All products in this class require clinical prior authorization:

- Diagnosis of cystic fibrosis with pseudomonas-related infection
- Age limit of 6 and older for Tobi solution, Bethkis solution, and Tobi Podhaler
- Age limit of 7 and older for Cayston
- “Pulse” dosing cycles of 28 days on drug, followed by 28 days off drug

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- If there has been a therapeutic failure to no less than a 28-day trial of at least one preferred medication

INHALED ANTIBIOTIC AGENTS

Aztreonam inhalation solution (Cayston®)

Tobramycin inhalation solution (Bethkis®, Tobi®)

Tobramycin inhalation powder (Tobi® Podhaler)

Respiratory Agents: Hereditary Angioedema

LENGTH OF AUTHORIZATIONS: 6 months

All products in this class require clinical prior authorization:

- Diagnosis of hereditary angioedema
- History of recurrent angioedema (without urticaria) within the past 6 months
- History of recurrent episodes of abdominal pain and vomiting within the past 6 months
- History of laryngeal edema within the past 6 months
- Positive family history of angioedema

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- If there has been one episode of angioedema during use of a preferred medication

HEREDITARY ANGIOEDEMA AGENTS

C1 Esterase Inhibitors (Berinert[®], Cinryze[®])

C1 Esterase Inhibitor, Recombinant (Ruconest[®])

Ecallantide (Kalbitor[®])

Icatibant Acetate (Firazyr[®])