DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

Under 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA), on formulary status, prior authorization (PA), pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) status are received from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

II. UF CLASS REVIEWS—GASTROINTESTINAL (GI)-2 AGENTS – CHRONIC IDIOPATHIC CONSTIPATION (CIC) AND CONSTIPATION-PREDOMINANT IRRITABLE BOWEL SYNDROME (IBS-C) AND GI-2 AGENTS – MISCELLANEOUS SUBCLASSES

P&T Comments

A. GI-2 Agents – CIC and IBS-C and GI-2 Agents – Miscellaneous Subclasses—Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the drugs used for chronic idiopathic constipation (CIC), constipation-predominant irritable bowel syndrome (IBS-C), and diarrhea-predominant irritable bowel syndrome (IBS-D). The products in the CIC/IBS-C subclass include linaclotide (Linzess), plecanatide (Trulance), and lubiprostone (Amitiza). The agents in the Miscellaneous subclass approved for IBS-D include rifaximin (Xifaxan) and eluxadoline (Viberzi).

The Committee reviewed new data available since the previous formulary decisions in 2011 and 2015.

The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 2 absent) the following:

Guidelines

- Guidelines from the American College of Gastroenterology (ACG) were updated for IBS in 2018. The ACG continues to recommend tricyclic antidepressants (TCAs) as a strong recommendation with high quality evidence for treating pain in IBS. Guidelines from several other organizations, were reviewed for treatment recommendations and for guiding development of the PA criteria.
- Most constipation-related guidelines include use of fiber, dietary and lifestyle modification, TCAs, antidiarrheals, and laxatives. Antispasmodics remain an option and are included in several guidelines.

- Guidelines for IBS-D include TCAs and antispasmodics/antidiarrheals as key components of therapy. In the 2018 ACG guidelines, TCAs remained a strong recommendation based on high quality evidence, while antispasmodics have a weak recommendation, based on low quality evidence. Other guidelines give a higher recommendation for antispasmodics, based on cost-effectiveness.

CIC and IBS-C Summary

- Linaclotide, plecanatide, and lubiprostone have all shown improvement in treating the constipation symptoms associated with IBS-C and CIC, compared to placebo.
- Lubiprostone (Amitiza) is indicated for CIC; however, its indication for IBS-C is limited to women. It is also indicated for opioid-induced constipation (OIC).
- In a 2018 systematic review from the American Journal of Gastroenterology, linaclotide (Linzess) and plecanatide (Trulance) demonstrated similar efficacy, safety, and adverse effects in treating IBS-C and CIC. Additionally, there was no statistically significant difference between Linzess compared to Trulance in terms of efficacy in CIC, occurrence of the adverse effect of diarrhea, or patient withdrawals from the study due to diarrhea.
- The difference in the incidence of diarrhea occurring with Trulance versus Linzess cannot be fairly compared because diarrhea was measured differently in the respective studies.

IBS-D Summary

- The ACG 2018 guidelines for IBS-D added eluxadoline (Viberzi) as a weak recommendation with moderate quality evidence; this is the same recommendation as for rifaximin (Xifaxan).
- FDA approval of Xifaxan for IBS-D was based on the TARGET 3 trial, which found it was modestly more effective than placebo in relieving IBS-D symptoms. Rifaximin appears to have a greater impact on reducing abdominal pain and has less impact on improving stool consistency.
- Rifaximin is not systemically absorbed and is therefore well tolerated with few safety concerns.
- Rifaximin has many potential off-label uses for which there is little or no supporting clinical data. At this time, unsupportable uses of rifaximin include SIBO, NASH, NAFLD, Crohn's disease, ulcerative colitis, diabetes, cirrhosis, Graft vs Host disease, primary sclerosing cholangitis, chronic abdominal pain, Celiac disease, bowel preparation for colonoscopy, constipation, colorectal cancer prevention, opioid-induced constipation, spontaneous bacterial peritonitis (SBP), and functional dyspepsia
- Eluxadoline (Viberzi) was evaluated in two placebo-controlled trials for IBS-D. Overall, it appears to improve stool consistency and has less of an impact on relieving abdominal pain.
- A 2017 United Kingdom National Institute for Clinical Effectiveness technology appraisal of eluxadoline recommended use only in refractory patients or those with contraindications to other treatments (e.g., antimotility agents,

antispasmodics, or TCAs). Additional recommendations include discontinuing eluxadoline if no response is seen after four weeks of therapy.

- The FDA issued a warning for eluxadoline in March 2017 to avoid use in patients who have had a cholecystectomy, due to an increased risk of pancreatitis and death.
- Eluxadoline limitations include numerous drug interactions and contraindications, lack of long-term safety data, and potential for abuse.

Overall Conclusion

- Studies with Linzess, Amitiza, and Trulance for IBS-C and CIC, and Xifaxan and Viberzi for IBS-D showed statistically significant results compared to placebo. However, for all the drugs, the clinical significance of the study results remains unclear, and all studies showed a significant placebo effect.
- At this time, comparative efficacy statements between the GI-2 drugs cannot be made, due to widely differing mechanisms of action, lack of head-to-head studies, lack of consistent diagnostic criteria, and variable subjective endpoints.
- Fidaxomicin (Dificid) and nitazoxanide (Alinia) have specific unique indications outside of CIC, IBS-C, and IBS-D and will remain on the formulary, as will the generic products, including alosetron, metronidazole, neomycin, and vancomycin.

B. GI-2 Agents – CIC and IBS-C and GI-2 Agents – Miscellaneous Subclasses— Relative Cost-Effectiveness Analysis and Conclusion

Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the GI-2 agents. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results for the CIC/IBS-C subclass showed that linaclotide (Linzess), lubiprostone (Amitiza), and plecanatide (Trulance) were all cost-effective agents.
- BIA was performed for the CIC/IBS-C subclass to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating linaclotide (Linzess), lubiprostone (Amitiza), and plecanatide (Trulance) as formulary demonstrated significant cost avoidance for the Military Health System (MHS).
- CMA results for the GI-2 Miscellaneous subclass showed that alosetron (Lotronex), eluxadoline (Viberzi), fidaxomicin (Dificid), nitazoxanide (Alinia), and rifaximin (Xifaxan) were all cost-effective agents.
- BIA was performed for the GI-2 Miscellaneous subclass to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating alosetron (Lotronex, generics), eluxadoline (Viberzi), fidaxomicin (Dificid), nitazoxanide (Alinia), and rifaximin (Xifaxan) as formulary demonstrated significant cost avoidance for the MHS.

C. GI-2 Agents – CIC and IBS-C and GI-2 Agents – Miscellaneous Subclasses—UF Recommendation

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following, based on clinical and cost effectiveness:

- UF

  CIC/IBS-C Subclass
  - linaclotide (Linzess)
  - lubiprostone (Amitiza)
  - plecanatide (Trulance)

  Miscellaneous Subclass
  - alosetron (Lotronex, generics)
  - eluxadoline (Viberzi)
  - rifaximin (Xifaxan)
  - nitazoxanide (Alinia)
  - fidaxomicin (Dificid)
  - vancomycin oral (generics)
  - neomycin (generics)
  - metronidazole (Flagyl, generics)

- NF
  - None

D. GI-2 Agents – CIC and IBS-C and GI-2 Agents – Miscellaneous Subclasses—Manual Prior Authorization (PA) Criteria

New manual PA criteria for lubiprostone (Amitiza) and linaclotide (Linzess) were recommended by the P&T Committee (16 for, 0 opposed, 0 abstained, 0 absent) for all new and current users, requiring a trial of drugs from at least two standard laxative classes first, unless contraindicated. Off-label use of Linzess for opioid-induced constipation (OIC) is allowed. The P&T Committee also recommended updating the current PA criteria for all new users of plecanatide (Trulance) to reflect the criteria for Amitiza and Linzess, with the exception that use of Trulance for OIC is not allowed.

The Committee also recommended updating the current PAs for rifaximin (Xifaxan) and eluxadoline (Viberzi) to require a trial of lifestyle modifications including dietary fiber and stress reduction. Any non-FDA-approved use for rifaximin is not allowed. There were no changes recommended to the PA criteria for rifaximin for hepatic encephalopathy or traveler's diarrhea.

1. Linzess and Amitiza

Manual PA criteria apply to all new and current users of Linzess and Amitiza.

Manual PA Criteria: Coverage is approved if all criteria are met:

- Age ≥ 18 years

- Patient has documented symptoms for ≥ 3 months
- Patient has diagnosis of IBS-C or CIC or OIC in adults with chronic, non-cancer pain
  - Amitiza or Linzess: Patient is currently taking an opioid if used for OIC
  - Amitiza: Patient is female if used for IBS-C
- Patient has documentation of failure of an increase in dietary fiber/dietary modification to relieve symptoms
- Patient has absence of GI obstruction
- Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes, defined as
  - osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories)
  - bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids;
  - stool softener (e.g., docusate);
  - stimulant laxative (e.g., bisacodyl, sennosides)
- Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik)

Linzess: Non-FDA-approved uses other than OIC are NOT approved.
Amitiza: Non-FDA-approved uses are NOT approved
Prior authorization expires after 1 year.

Renewal PA Criteria: Coverage will be approved for 1 year for continuation of therapy if:
- Patient has had improvement in constipation symptoms and
- Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik)

2. Trulance
November 2018 updates are in BOLD and strikethrough.

Manual PA criteria apply to all new users of Trulance.

Manual PA criteria: Coverage is approved if all criteria are met:
- Patient is ≥ 18 years of age
- **Patient has documented symptoms for ≥ 3 months**
- Patient has diagnosis of IBS-C or CIC
- Patient has absence of GI obstruction
- **Patient has documentation of failure of an increase in dietary fiber/dietary modification**
- **Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes, defined as**
  - **osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories)**

    - **bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids**
    - **stool softener (e.g., docusate)**
    - **stimulant laxative (e.g., bisacodyl, sennosides)**
- **Patient is not taking any of these agents concomitantly (Trulance, Amitiza, Linzess, Symproic, Relistor, or Movantik)**
- ~~Must have failed/intolerant to linaclotide (Linzess)~~
- ~~Must have failed/intolerant to lubiprostone (Amitiza)~~

Non-FDA-approved uses are NOT approved.
Prior authorization expires after 1 year.

Renewal PA Criteria: Coverage will be approved for 1 year for continuation of therapy if:

- Patient has had improvement in constipation symptoms and
- Patient is not taking any of these agents concomitantly (Amitiza, Linzess, Symproic, Trulance, Relistor, or Movantik)

3. Viberzi
November 2018 updates are in BOLD and strikethrough.

Manual PA criteria apply to all new users of Viberzi.

Manual PA criteria: Coverage is approved if all criteria are met:

- Age ≥ 18 years
- Written by or in consultation with a gastroenterologist
- Patient has no history of alcoholism, alcohol abuse, or alcohol addiction, or in patients who drink alcohol, they drink < 3 alcoholic beverages per day
- Patient has no history of marijuana use or illicit drug use in the previous 6 months
- Patient does not have severe hepatic impairment (Child-Pugh C)
- Patient has a documented diagnosis of IBS-D
- **Patient has tried and failed dietary changes (including fiber), stress reduction, or cognitive behavioral therapy**
- Patient has not had a cholecystectomy
- The patient has had failure, intolerance, or contraindication to at least one antispasmodic/**antidiarrheal** agent; e.g., dicyclomine, Librax, hyoscyamine, Donnatal, loperamide
- The patient has had failure, intolerance, or contraindication to at least one TCA (to relieve abdominal pain); e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline
- ~~The patient has tried and failed rifaximin~~

Non-FDA approved uses are NOT approved.
~~PA does not expire.~~ PA expires after 4 months.

Renewal PA Criteria: Coverage will be approved for 1 year if:

- The patient has had documented improvement in IBS-D symptoms

4. Xifaxan

November 2018 updates for the indication of IBS-D are in BOLD. No changes for the indications of hepatic encephalopathy or traveler's diarrhea.

Manual PA criteria apply to all new users of Xifaxan 550 mg for IBS-D.

Manual PA criteria: Coverage is approved if all criteria are met:

- Age ≥ 18 years
- Patient has a diagnosis of IBS-D, without constipation with symptoms of moderate abdominal pain and bloating
- **The prescription is written by or in consultation with a gastroenterologist**
- **Patient has documentation of failure of dietary changes (including fiber), stress reduction, or cognitive behavioral therapy**
- Patient has tried and failed or had intolerance, or a contraindication to at least one antispasmodic/antidiarrheal agent (e.g., dicyclomine [Bentyl], Librax, hyoscyamine [Levsin], Donnatal, imodium [Loperamide])
- Patient has tried and failed or had intolerance or a contraindication to at least one tricyclic antidepressant (e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline)

Non-FDA-approved uses are NOT approved including: small intestinal bacterial overgrowth (SIBO), non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD), spontaneous bacterial peritonitis (SBP), functional dyspepsia, diabetes, cirrhosis (ascites/alcohol-related), graft vs host disease, primary sclerosing cholangitis, Celiac disease, ulcerative colitis, Crohn's disease, diverticular disease, bowel preparation, constipation, colorectal cancer prevention, opioid-induced constipation, chronic abdominal pain, or other disease states.

~~PA expires after 6 months~~. **Prior authorization expires after 1 year. No renewal allowed. Note that a maximum of 3 treatment courses for IBS-C are allowed in 1 year.**

E. GI-2 Agents – CIC and IBS-C and GI-2 Agents – Miscellaneous—UF and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service, and 2) DHA send letters to beneficiaries who are affected by the UF decision.

III. UF CLASS REVIEWS—GI-2 AGENTS – CIC AND IBS-C AND GI-2 AGENTS – MISCELLANEOUS SUBCLASSES

BAP Comments

A. GI-2 Agents – CIC and IBS-C and GI-2 Agents – Miscellaneous Subclasses—UF Recommendation

The P&T Committee recommended the formulary status for the GI-2 Agents as discussed above.

- UF

  CIC/IBS-C Subclass
  - Linzess
  - Amitiza
  - Trulance

  Miscellaneous Subclass
  - Lotronex, generics
  - Viberzi
  - Xifaxan
  - Alinia
  - Dificid
  - vancomycin oral (generics)
  - neomycin (generics)
  - Flagyl, generics
- NF
  - None

BAP Comment: ☐ Concur ☐ Non-concur

B. GI-2 Agents – CIC and IBS-C and GI-2 Agents – Miscellaneous Subclasses—Manual PA Criteria

The P&T Committee recommended new manual PA for new and current users of Amitiza and Linzess, and updates to the current criteria for Trulance, Xifaxan and Viberzi, as discussed previously.

BAP Comment: ☐ Concur ☐ Non-concur

C. GI-2 Agents – CIC and IBS-C and GI-2 Agents – Miscellaneous Subclasses—UF and PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service, and 2) DHA send letters to beneficiaries who are affected by the UF decision.

BAP Comment: ☐ Concur ☐ Non-concur

IV. NEUROLOGICAL AGENTS MISCELLANEOUS – MOVEMENT DISORDERS SUBCLASS

P&T Comments

A. Neurological Agents Miscellaneous – Movement Disorders Subclass—Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the Movement Disorder subclass, which includes the vesicular monoamine transporter type 2 (VMAT2) inhibitors. The drugs evaluated were tetrabenazine (Xenazine, generics), deutetrabenazine (Austedo), and valbenazine (Ingrezza). Tetrabenazine and deutetrabenazine are approved for treating Huntington's disease chorea, while both deutetrabenazine and valbenazine are indicated for tardive dyskinesia.

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

Huntington's disease (HD) chorea

- Professional clinical practice guidelines from the American Academy of Neurology (AAN) in 2012 listed tetrabenazine as likely effective in decreasing chorea associated with Huntington's disease to a very important degree, based on level B evidence.
- There are no head-to-head trials comparing tetrabenazine with Austedo. However, a published indirect comparison concluded that the two drugs do not differ in efficacy, based on low-quality evidence.
- With regard to safety, both tetrabenazine and Austedo carry a black box warning for increased depression and suicidality when used for Huntington's disease chorea.

- Common adverse effects associated with tetrabenazine include sedation, somnolence, insomnia, and depression. The package insert for Austedo lists fewer neuropsychiatric adverse effects than tetrabenazine.
- There is insufficient evidence to determine whether there is a clinically significant difference in safety between tetrabenazine and deutetrabenazine (Austedo), due to the lack of head-to-head trials and conflicting results from two published indirect comparisons that used the same data.

Tardive dyskinesia

- Guidelines from the AAN in 2016 graded tetrabenazine as having level C evidence that it reduces symptoms and may be considered in treating tardive dyskinesia. Based on level B evidence, clonazepam was considered probably effective in decreasing tardive dyskinesia symptoms in the short-term, and ginkgo biloba extract was also probably useful, with the data limited to an inpatient population.
- A 2018 systematic review from the Journal of Neurological Science considered Austedo and Ingrezza as effective for tardive dyskinesia, based on level A evidence. The authors also recommended that for patients who have no access to Austedo or Ingrezza, to consider tetrabenazine, despite the lesser evidence available than with clonazepam or ginkgo biloba.
- A report from the Institute for Clinical Effectiveness Research (ICER) found promising but inconclusive data for both Austedo and Ingrezza. Individual placebo-controlled trials with the two drugs reported statistically significant differences over placebo in measures on the Abnormal Involuntary Movement Scale (AIMS), but inconclusive results on both the Patients' and Clinicians' Global Impression of Change scores.
- There is insufficient evidence to determine whether there is a clinically relevant difference in efficacy between Austedo and Ingrezza when used for tardive dyskinesia.
- In terms of safety, Austedo lacks a black box warning for depression and suicidality when used for treating symptoms of tardive dyskinesia. Both Austedo and Ingrezza report similar adverse events, including QTc interval prolongation.

Other factors

- There is a high degree of therapeutic interchangeability between tetrabenazine and deutetrabenazine (Austedo) for treating Huntington's disease chorea based on efficacy and safety.
- There is a high degree of therapeutic interchangeability between valbenazine (Ingrezza) and deutetrabenazine (Austedo) for treating tardive dyskinesia based on similar efficacy and safety.

B. Neurological Agents Miscellaneous – Movement Disorders Subclass—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed to evaluate the Movement Disorder agents. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that generic tetrabenazine was the most cost-effective Movement Disorder drug, followed by valbenazine (Ingrezza), deutetrabenazine (Austedo), and brand tetrabenazine (Xenazine).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating generic tetrabenazine, valbenazine (Ingrezza), and deutetrabenazine (Austedo) as formulary demonstrated significant cost avoidance for the MHS.

C. Neurological Agents Miscellaneous – Movement Disorders Subclass—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- UF
  - tetrabenazine
  - deutetrabenazine (Austedo)
  - valbenazine (Ingrezza)
- NF
  - None

D. Neurological Agents Miscellaneous – Movement Disorders Subclass—Manual PA Criteria

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the current manual PA criteria for deutetrabenazine (Austedo) and valbenazine (Ingrezza) that have been in place since 2017. PA was not recommended for generic tetrabenazine.

For Huntington's disease chorea, the PA for Austedo will still require a trial of generic tetrabenazine first, based on the AAN guidelines and cost-effectiveness. For both Austedo and Ingrezza, updates to the PA included adding the package insert warning for QTc prolongation; removing the requirement for a trial of gingko biloba and clonazepam first in patients with tardive dyskinesia, based on the clinical practice guidelines; and adding renewal PA criteria after one year showing efficacy and continued evaluation of the patient for depression and suicidality.

1. Austedo

Changes from the November 2018 meeting are in bold and strikethrough
Manual PA criteria apply to all new users of Austedo.

Manual PA Criteria: Coverage is approved for initial therapy for one year if all criteria are met:

- **Patient does not have congenital or acquired long QT syndrome or arrhythmias associated with QT prolongation**
- Patient does not have severe hepatic impairment

- Patient is not taking any of the following: MAOI within the past 14 days, reserpine, CYP3A4 inducers, or another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine)

Huntington's Disease Chorea

- Prescribed by or in consultation with a neurologist
- Patient has a diagnosis of chorea associated with Huntington's disease
- Patient does ~~is~~ not have ~~actively~~ suicidal ideation
- Patient does not have depression or is being adequately treated for depression
- Patient has had an adequate trial of tetrabenazine for 12 weeks and has experienced treatment failure or experienced an adverse event that is not expected to occur with Austedo

Tardive Dyskinesia

- Age ≥ 18 years
- Prescribed by or in consultation with a neurologist or psychiatrist
- Patient does not have ~~is actively~~ suicidal ideation
- **Patient does not have depression or is being adequately treated for depression**
- Patient has moderate to severe tardive dyskinesia **causing functional impairment** along with schizophrenia, schizoaffective disorder, or a mood disorder
- ~~Provider has considered gingko biloba or clonazepam~~
- **Provider has considered a dose reduction, tapering, or discontinuation of the dopamine receptor blocking agent suspected of causing the symptoms**

PA expires in one year.
Non-FDA-approved uses are NOT approved (e.g., Tourette's, ~~tardive dyskinesia,~~ dystonia).

Renewal PA Criteria: Coverage is approved indefinitely for continuation of therapy if all criteria are met:

- ~~Patient has demonstrated improvement in chorea based on clinician assessment and is being monitored for depression and suicidal ideation~~

- **Huntington's Disease Chorea: Patient has demonstrated improvement in symptoms based on clinician assessment. Patient is being monitored for depression and suicidal ideation.**

- **Tardive Dyskinesia: Patient has demonstrated improvement in symptoms based on an improvement of at least 2 on the AIMS. Patient is being monitored for depression and suicidal ideation.**

2. Ingrezza
Changes from the November 2018 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Ingrezza.

Manual PA Criteria: Coverage is approved if all criteria are met:

- Age > 18 years
- Prescribed by or in consultation with a neurologist or psychiatrist
- Patient does not have ~~is actively~~ suicidal ideation
- **Patient does not have depression, or is being adequately treated for depression**
- Patient has moderate to severe tardive dyskinesia **causing functional impairment** along with schizophrenia, schizoaffective disorder, or a mood disorder
- ~~Patient has had an adequate trial and has failed or has a contraindication to tetrabenazine or deutetrabenazine~~
- ~~Provider has considered use of clonazepam and gingko biloba~~
- **Provider has considered a dose reduction, tapering, or discontinuation of the dopamine receptor blocking agent suspected of causing the symptoms**
- Patient does not have congenital **or acquired** long QT syndrome or arrhythmias associated with QT prolongation
- Patient is not taking any of the following:
  - MAOI, CYP3A4 inhibitors, CYP2D6 inhibitors, CYP3A4 inducers, another VMAT2 inhibitor (e.g., tetrabenazine, deutetrabenazine)

Non-FDA-approved uses are NOT approved (i.e., Tourette's, dystonia).

~~PA does not expire~~
PA expires in one year.

Renewal PA Criteria: **Coverage is approved indefinitely for continuation of therapy if all criteria are met:**

- **Patient has demonstrated improvement in symptoms based on an improvement of at least 2 on the Abnormal Involuntary Movement Scale (AIMS). Patient is being monitored for depression and suicidal ideation.**

E. Neurological Agents Miscellaneous – Movement Disorders Subclass—UF and PA Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after the signing of the minutes in all points of service (POS).

V. NEUROLOGICAL AGENTS MISCELLANEOUS – MOVEMENT DISORDERS SUBCLASS

BAP Comments

A. Neurological Agents Miscellaneous – Movement Disorders Subclass—UF Recommendation

The P&T Committee recommended the formulary status, as stated above.

- UF
  - tetrabenazine
  - Austedo
  - Ingrezza
- NF
  - None

BAP Comment: ☐ Concur ☐ Non-concur

B. Neurological Agents Miscellaneous – Movement Disorders Subclass—Manual PA Criteria

The P&T Committee recommended updates to manual PA criteria for Austedo and Ingrezza as discussed above.

BAP Comment: ☐ Concur ☐ Non-concur

C. Neurological Agents Miscellaneous – Movement Disorders Subclass—UF and PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday 30 days after the signing of the minutes in all points of service.

BAP Comment: ☐ Concur ☐ Non-concur

VI. NEWLY APPROVED DRUGS PER 32 CFR 199.21(G)(5)

P&T Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF:
    - cannabidiol oral solution (Epidiolex) – Anticonvulsants-Antimania Agent for Lennox-Gastaut Syndrome or Dravet Syndrome
    - dacomitinib (Vizimpro) – Oncologic Agent for Non-Small Cell Lung Cancer (NSCLC)
    - darunavir/cobicistat/emtricitabine/tenofovir alafenamide (TAF) (Symtuza) – Combination Antiretroviral for HIV
    - darunavir/lamivudine/tenofovir disoproxil fumarate (TDF) (Delstrigo) – Combination Antiretroviral for HIV
    - doravirine (Pifeltro) – Antiretroviral for HIV
    - duvelisib (Copiktra) – Oncologic Agent for Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)
    - fremanezumab-vfrm injection (Ajovy) – Migraine Agent (calcitonin gene-related peptide [CGRP]) for Migraine Headache Prophylaxis
    - galcanezumab-gnlm injection (Emgality) – Migraine Agent (calcitonin gene-related peptide [CGRP]) for Migraine Headache Prophylaxis
    - glycopyrronium 2.4% topical cloth (Qbrexza) – Antiperspirant for Primary Axillary Hyperhidrosis
    - ivosidenib (Tibsovo) – Oncologic Agent for Acute Myelogenous Leukemia (AML)
    - lanadelumab (Takhzyro) injection – Corticosteroid-Immune Modulator for Hereditary Angioedema (HAE) Prophylaxis
    - lumacaftor/ivacaftor granules (Orkambi) – Cystic Fibrosis Agent
    - lusutrombopag (Mulpleta) – Hematologic Agent: Platelets for Thrombocytopenia in Chronic Liver Disease
    - metoprolol extended-release (ER) capsules (Kapspargo Sprinkle) – Beta-Blocker
    - migalastat (Galafold) – Miscellaneous Metabolic Agent for Fabry Disease
    - PEG3350/Na ascorbate/NaSO4/ascorbic acid/NaCl/KCl powder packets (Plenvu) – Laxatives-Cathartics-Stool Softener for Bowel Prep
    - pegfilgrastim-jmdb injection (Fulphila) – Hematologic Agent: White Blood Cell Stimulant
    - PEGylated Factor VIII (Jivi) – Antihemophilic Factor
    - sodium zirconium cyclosilicate packet for oral suspension (Lokelma) – Binders Chelators Overdose Agents Hyperkalemia

- NF:
    - adapalene 0.1% topical solution (external pad/swab) (Plixda) – Topical Acne Agent
    - adapalene 0.1% topical solution – Topical Acne Agent
    - amikacin liposome inhaled suspension (Arikayce) – Aminoglycoside Antibiotic for Mycobacterium Avium Complex (MAC)
    - butalbital 50 mg and acetaminophen 300 mg capsules – Analgesics and Combinations
    - doxycycline monohydrate capsules (Okebo) – Oral Tetracycline Agent
    - elagolix sodium (Orilissa) – Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists for Endometriosis
    - filgrastim-aafi injection (Nivestym) – Hematologic Agent: White Blood Cell Stimulant
    - lidocaine 1.8% topical patch (ZTlido) – Topical Pain Agent
    - minocycline ER tablets (Minolira) – Oral Tetracycline Agent
    - ozenoxacin 1% cream (Xepi) – Quinolone Antibiotic for Impetigo
    - tildrakizumab-asmn injection (Ilumya) – Targeted Immunomodulatory Biologic (TIB) for Plaque Psoriasis
    - tretinoin 0.05% topical lotion (Altreno) – Topical Acne Agent

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- TIBs: Applying the same manual PA criteria for Ilumya in new users, as is currently in place for the other non-step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for Ilumya, a trial of both secukinumab (Cosentyx) and ustekinumab (Stelara) is required if the patient cannot be treated with Humira.
- Topical Acne Agents: Applying the same manual PA criteria for adapalene topical solution, adapalene 0.1% external swab/pad (Plixda), and tretinoin 0.05% topical lotion (Altreno) in new and current users as is currently in place for the other non-step-preferred topical retinoid acne agents. Patients must first try at least three step-preferred topical acne products.
- Oral Tetracyclines: Applying the same manual PA criteria for doxycycline monohydrate ER capsules (Okebo) and minocycline ER 105 mg and 135 mg tablets (Minolira) that is currently in place for the other non-step-preferred oral tetracyclines. Patients must first try one generic doxycycline IR product, either the hyclate or monohydrate salt (for Okebo) or one generic minocycline IR product (for Minolira).
- CGRP Migraine Headache Prophylaxis Drugs: Applying manual PA criteria to new users of Ajovy and Emgality as is currently in place for erenumab injection (Aimovig).
- Applying manual PA criteria to new users of Orkambi granules as is currently in place for Orkambi tablets to include the FDA-approved age range, and to not

allow concomitant use of the tablets and granules or concomitant use of Orkambi with other CF drugs, including Kalydeco or Symdeko.

- Applying manual PA criteria to new users of Arikayce, Copiktra, Epidiolex, Kapspargo Sprinkle, Mulpleta, Takhzyro, Tibsovo, Vizimpro, and Xepi.
- Applying manual PA criteria to new and current users of butalbital 50 mg/acetaminophen 300 mg capsule, Galafold, Orilissa, Qbrexza, and ZTlido.

Full PA Criteria for the Newly Approved Drugs per 32 CFR 199.21(g)(5)

1. **adapalene 0.1% topical solution, adapalene 0.1% topical solution external pad/swab (Plixda), and tretinoin 0.05% topical lotion (Altreno)**

   Automated PA Criteria:
   - The patient has filled a prescription for at least three step-preferred topical acne products including at least two different strengths of tretinoin and 0.1% adapalene (for adapalene 0.1% solution and Plixda) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days.

   Manual PA Criteria: If automated PA criteria are not met, adapalene 0.1% topical solution, Plixda, and tretinoin 0.05% topical lotion (Altreno) will be approved if:

   - The patient has a diagnosis of acne vulgaris AND
   - Patient has tried and failed at least three step-preferred topical acne products, including at least two different strengths of tretinoin and 0.1% adapalene (for adapalene 0.1% topical solution and Plixda) (e.g., generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene, or sulfacetamide sodium/sulfur) OR
   - The patient has experienced an adverse reaction or an inadequate response with formulary, step-preferred topical tretinoin and adapalene agents that is not expected to occur with the non-formulary, non-step-preferred product

   Non-FDA-approved uses are NOT approved.
   PA expires in 1 year. PA renewal is not allowed.

2. **amikacin sulfate liposomal inhalation suspension (Arikayce)**

   Manual PA criteria apply to all new users of Arikayce.

   Manual PA Criteria: Arikayce is approved if ALL of the following criteria are met:
   - Age $\geq$ 18
   - Prescription is written by or in consultation with an Infectious Disease Specialist and/or Pulmonologist.

- Patient has a diagnosis of refractory *Mycobacterium avium* complex (MAC) lung disease as defined as a patient who does not achieve negative sputum cultures after a minimum of 6 consecutive months of conventional therapy.
- Patient continues to have a susceptible infection to amikacin.
- Patient is on a concomitant multidrug background (baseline) regimen therapy.
- Provider must explain why the patient cannot use IV amikacin (fill in the blank)
- Provider acknowledges and patient has been informed that Arikayce carries a boxed warning for risk of increased respiratory adverse reactions that can lead to hospitalization.
- Provider acknowledges and patient has been informed that warnings and precautions of Arikayce include hypersensitivity pneumonitis, hemoptysis, bronchospasm, exacerbation of underlying pulmonary disease, ototoxicity, nephrotoxicity, neuromuscular blockade, and embryo-fetal toxicity.
- Provider acknowledges (and patient has been informed) the patient will be monitored for adverse reactions that include but are not limited to: (from package insert occurring at an incidence of ≥ 10% and higher than control) dysphonia, cough, bronchospasm, hemoptysis, ototoxicity, upper airway irritation, musculoskeletal pain, fatigue/asthenia, exacerbation of underlying pulmonary disease, diarrhea, and nausea.

Non-FDA-approved uses are NOT approved (including for *Pseudomonas Aeruginosa*).
PA does not expire.

3. butalbital 50 mg/acetaminophen 300 mg capsule

Manual PA criteria apply to all new and current users of butalbital 50 mg/acetaminophen 300 mg capsules.

Manual PA Criteria: Coverage will be approved for butalbital 50 mg/acetaminophen 300 mg capsules if all criteria are met:

- Patient has a diagnosis of tension or muscle headaches
- Patient cannot tolerate generic oral tablet or capsule formulations of butalbital/acetaminophen or butalbital/acetaminophen/caffeine.

Non-FDA-approved uses are NOT approved.
PA does not expire.

4. cannabidiol oral solution (Epidiolex)

Manual PA criteria apply to all new users of Epidiolex.

Manual PA Criteria: Epidiolex is approved if all criteria are met:

- Must be prescribed by a pediatric neurologist or neurologist
- Patient has been diagnosed with either Lennox-Gastaut Syndrome or Dravet Syndrome

Non-FDA-approved uses are NOT approved.
PA does not expire.

5. dacomitinib (Vizimpro)

Manual PA criteria apply to all new users of Vizimpro.

Manual PA Criteria: Vizimpro is approved if all criteria are met:

- Patient ≥ 18 years old
- Patient has histologically or cytopathologically confirmed stage IIIB/IV or recurrent non-small cell lung cancer with the presence of at least one documented epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutation as detected by an FDA-approved test
- Patient has no evidence of active infection, non-infectious pneumonitis, nor interstitial lung disease
- Patient has no previous use of an epidermal growth factor kinase inhibitor (e.g., Tarceva, Iressa, Gilotrif, or Tagrisso)
- Drug is prescribed by or in consultation with a hematologist/oncologist

Non-FDA-approved uses are NOT approved.
PA does not expire.

6. doxycycline monohydrate ER 50, 75 and 100 mg capsules (Okebo) and minocycline 105 and 135 mg ER tablets (Minolira)

PA applies to both new and current users of Okebo and Minolira.

Automated PA Criteria:

- Patient has filled a prescription for one generic IR doxycycline (either hyclate or monohydrate salt) **AND** one generic minocycline IR product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 180 days

Manual PA Criteria: If automated PA criteria are not met, the non-step-preferred product is allowed if:

Acne Vulgaris or Rosacea

- For **Okebo:** The patient has tried and had an inadequate response to or failed to tolerate the following:
  - one generic immediate-release doxycycline product (hyclate or monohydrate salt) AND
  - one generic immediate-release minocycline product

- For **Minolira**: The patient has acne with inflammatory lesions AND
  - the patient cannot tolerate generic minocycline IR due to gastrointestinal adverse events

Susceptible Infections

- For **Okebo**: if used for susceptible infections, the patient has failed or had clinically significant adverse events to generic IR doxycycline

Non-FDA-approved uses are NOT approved.
PA expires in 1 year.

Renewal Criteria: Okebo or Minolira will be approved for an additional year if:

- The patient's therapy has been re-evaluated within the last 12 months
- The patient is tolerating treatment, and there is continued medical need for the medication
- The patient has had disease stabilization or improvement in disease on therapy

7. duvelisib (Copiktra)

Manual PA criteria apply to all new users of Copiktra.

Manual PA criteria: Copiktra is approved if all criteria are met:

- Patient ≥ 18 years old
- Patient has evidence and pathologic confirmation of relapsed or refractory chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) or relapsed or refractory follicular lymphoma (FL)
- Patient has undergone at least two prior systemic therapies
- Provider is aware and has informed patient of the risk of serious, life-threatening, and fatal infections, including *Pneumocystis jiroveci* pneumonia (PJP) and cytomegalovirus (CMV); diarrhea; colitis; cutaneous reactions, including drug rash with eosinophilia and systemic symptoms (DRESS) and Stevens Johnson Syndrome spectrum reactions, including Toxic Epidermal Necrolysis; pneumonitis; hepatotoxicity; and neutropenia
- Patient has no evidence of active infection, diarrhea, colitis, serious cutaneous disease, pneumonitis, hepatitis, significantly elevated liver-associated enzymes, nor neutropenia
- Female patients of childbearing age are not pregnant confirmed by (-) HCG and agree to use contraception
- Male patients are informed that Copiktra may cause male infertility
- Drug is prescribed by a hematologist/oncologist
- Prescriber agrees to advise patient of the toxicities of the drug, as outlined in the REMS program found at http://www.copiktrarems.com

Non-FDA-approved uses are NOT approved.
PA does not expire.

8. elagolix (Orilissa)

Manual PA applies to all new and current users of elagolix (Orilissa).

Manual PA Criteria: Elagolix is approved if all criteria are met:

- Age ≥ 18
- Patient is a premenopausal woman with endometriosis
- Patient has had inadequate relief after at least three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives, unless contraindicated
- Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist
- Patient is not pregnant. Pregnancy test required.
- Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment
- Patient does not have severe hepatic impairment (Child-Pugh Class C)
- Patient does not have osteoporosis
- Patient is on concurrent calcium supplementation.
- Patient is not using Orilissa concomitantly with cyclosporine or gemfibrozil

Non-FDA-approved uses are NOT approved.
PA Expiration 9 months; Renewal expiration 24 months

Renewal Criteria: PA will be approved for an additional 15 months (lifetime usage not to exceed 24 months) if all criteria are met:

- The patient meets the original PA criteria
- Patient does not have moderate hepatic impairment (Child-Pugh Class C)
- Patient is taking the Orilissa 150 mg dose (note that the 200 mg dose is only approved for up to 6 months)

9. fremanezumab-vfrm injection (Ajovy) and galcanezumab-gnlm injection (Emgality)

Manual PA criteria apply to all new users of Ajovy and Emgality.

Manual PA Criteria: Ajovy or Emgality is approved if all criteria are met:

- Patient ≥ 18 years old and not pregnant
- Must be prescribed by or in consultation with a neurologist
- Patient has a migraine diagnosis with at least 8 migraine days per month for 3 months
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:

- Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
- Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol
- Prophylactic antidepressants: amitriptyline, venlafaxine

- Concurrent use with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality) is not allowed
- For Emgality, loading doses will be allowed

Non-FDA-approved uses are NOT approved.
PA expires after 6 months.

Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if:

- The patient has shown improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication)

10. glycopyrronium 2.4% topical cloth (Qbrexza)

Manual PA criteria apply to all new and current users of Qbrexza.

Manual PA Criteria: Coverage is approved if all criteria are met:

- Age ≥ 9 years
- Patient has had a diagnosis of primary axillary hyperhidrosis for ≥ 6 months
- Patient has tried and failed at least one topical 20% or higher aluminum salt (either OTC or prescription) and at least one additional option (e.g., Botox, MiraDry, iontophoresis, oral anticholinergics [glycopyrrolate, oxybutynin, propantheline], propranolol, clonidine, or diltiazem)
- Prescribed by a dermatologist

Non-FDA-approved uses are NOT approved. Not for palmar, plantar, facial, or other forms of hyperhidrosis.
PA does not expire.

11. ivosidenib (Tibsovo)

Manual PA criteria apply to all new users of Tibsovo.

Manual PA Criteria: Tibsovo is approved if all criteria are met:

- Patient ≥ 18 years old
- Has laboratory evidence of relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test
- The patient will be monitored for differentiation syndrome
- The patient will be monitored for Guillain-Barre syndrome
- Prescribed by or in consultation with a hematologist/oncologist

For non-FDA-approved uses, please cite supporting literature.
PA does not expire.

12. lanadelumab-flyo (Takhzyro)

Manual PA applies to all new users of Takhzyro.

Manual PA Criteria: lanadelumab is approved if all apply:

- The patient is ≥ 12 years old
- Patient is not pregnant or breastfeeding
- The patient must be diagnosed with hereditary angioedema (HAE) Type I, II, or III (HAE with normal C1-esterase inhibitor)
- The drug is prescribed by an allergist, immunologist, or rheumatologist or in consultation with an HAE specialist
- The patient must experience baseline of ≥ 2 HAE attacks per month
- The patient has tried and failed an attenuated androgen (danazol) OR
  - Patient has experienced or is expected to experience serious adverse effects from the use of an androgen (e.g., virilization of women, stroke, myocardial infarction, venous thromboembolism) OR
  - Patient is female of childbearing age

Non-FDA-approved uses NOT approved.
PA does not expire.

13. lidocaine 1.8% topical patch (ZTlido)

Manual PA applies to all new and current users of lidocaine 1.8% topical patch (ZTlido).

Manual PA Criteria: ZTlido is approved if:

- The patient has a diagnosis of post-herpetic neuralgia AND
- Provider must explain why patient cannot use lidocaine 5% patch (Lidoderm, generics).
  - Acceptable response: patient has failed an adequate course of Lidoderm
  - Not an acceptable response: Adhesive issues with Lidoderm is not a valid reason for ZTlido approval.

Non-FDA-approved uses are NOT approved.
PA does not expire.

14. lumacaftor/ivacaftor (Orkambi granules)

Manual PA criteria apply to all new users of Orkambi granules.

Manual PA Criteria: Coverage is approved if all criteria are met:

- Orkambi is prescribed for the treatment of cystic fibrosis in an age appropriate patient population according to the product label.
  - For Orkambi granules – the patient is between the ages of 2 to 5 years, or the patient is older than 5 years with documented swallowing difficulties
  - For Orkambi tablets – the patient is 6 years of age or older
- The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected/confirmed by an FDA-approved test
- Concomitant use of Orkambi granules with Orkambi tablets is not allowed.
- Concomitant use of Orkambi granules or tablets is not allowed with ivacaftor (Kalydeco) or tezacaftor/ivacaftor (Symdeko).

Non-FDA-approved uses are NOT approved, including:
- Patients who are heterozygous for the F508del mutation in the CFTR gene

PA does not expire.

15. lusutrombopag (Mulpleta)

Manual PA criteria apply to all new users of Mulpleta.

Manual PA Criteria: Mulpleta is approved if all criteria are met:
- Patient ≥ 18 years old
- Diagnosed with liver disease that has caused severe thrombocytopenia (platelet < 50 x 109/L)
- Will be undergoing a procedure with *a moderate to high bleeding risk* within 8-14 days
- Has no evidence of current thrombosis
- Prescribed by or in consultation with a gastroenterologist

Non-FDA-approved uses are NOT approved.
PA expires in 60 days.
PA renewal is not allowed.

16. metoprolol succinate ER capsules (Kapspargo Sprinkle)

PA does not apply to patients between the ages of 6 to 18 years.

Manual PA criteria apply to all new users of Kapspargo older than 18 years of age.

Manual PA Criteria: Coverage is approved if all criteria are met:
- Age > 18 years of age
- Diagnosis of hypertension, angina pectoris, or heart failure
- Drug will be dosed at a maximum of once daily

- Provider must explain why the patient requires metoprolol succinate sprinkle and cannot take alternative formulary beta blockers

Non-FDA-approved uses are NOT approved.
PA does not expire.

17. migalastat (Galafold)

Manual PA applies to all new and current users of migalastat (Galafold).

Manual PA Criteria: Migalastat is approved if all criteria are met:

- Age ≥ 18 years old
- Has laboratory evidence of GLA gene variant based on *in vitro* assay data
- Galafold is prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease
- Must not be used concomitantly with Fabrazyme

Non-FDA-approved uses are NOT approved.
PA does not expire.

18. ozenoxacin 1% cream (Xepi)

Manual PA criteria apply to all new users of Xepi.

Manual PA Criteria: Xepi is approved if ALL criteria are met:

- Patient is 2 months or age or older
- Patient has a diagnosis of impetigo
- Patient has failed a trial of mupirocin 2% ointment or cream (unless contraindicated or clinically significant adverse effects have been experienced)
- Patient has a contraindication to or has failed a trial of an oral antibiotic for (e.g., cephalexin, dicloxacillin, clindamycin)
- The Xepi dose will not exceed twice daily topical application for 5 days

Non-FDA-approved uses are NOT approved.
Prior authorization expires after 1 month; renewal will require PA to be completed again.

19. tildrakizumab (Ilumya)

Manual PA criteria apply to all new and current users of Ilumya. The patient must have tried Humira, Cosentyx, AND Stelara first.

Manual PA Criteria: Ilumya is approved if all criteria are met:

- The patient has a contraindication or has had an inadequate response to Humira, Cosentyx, AND Stelara
- The patient has had an adverse reaction to Humira, Cosentyx, AND Stelara that is not expected with requested non-step-preferred TIB

- Patient ≥ 18 years old
- The patient is diagnosed with moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy
- Patient has tried and had an inadequate response to non-biologic systemic therapy) (e.g., methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])
- Coverage NOT provided for concomitant use with other TIBs
- The patient has had a negative TB test result in past 12 months (or TB is adequately managed)

Non-FDA-approved uses are NOT approved.
PA does not expire.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date upon the first Wednesday 30 days after signing of the minutes in all points of service.

VII. NEWLY APPROVED DRUGS PER 32 CFR 199.21(G)(5)

BAP Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended the formulary status for the new drugs as stated previously.

- UF:
  - Epidiolex
  - Vizimpro
  - Symtuza
  - Pifeltro
  - Delstrigo
  - Copiktra
  - Ajovy
  - Emgality
  - Qbrexza
  - Tibsovo
  - Takhzyro
  - Orkambi
  - Mulpleta
  - Kapspargo Sprinkle
  - Galafold
  - Plenvu
  - Fulphila
  - Jivi
  - Lokelma

- NF:
    - Plixda
    - adapalene 0.1% topical solution
    - Arikayce
    - butalbital 50 mg and acetaminophen 300 mg capsules
    - Okebo
    - Orilissa
    - Nivestym
    - ZTlido
    - Minolira
    - Xepi
    - Ilumya
    - Altreno

BAP Comment: ☐ Concur ☐ Non-concur

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended the PA criteria for the new drugs as stated previously

BAP Comment: ☐ Concur ☐ Non-concur

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan

The P&T Committee recommended an effective date upon the first Wednesday 30 days after signing of the minutes in all points of service.

BAP Comment: ☐ Concur ☐ Non-concur

VIII. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA AND STEP THERAPY

P&T Comments

A. Updated PA Criteria and Step Therapy

Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications and safety. The updated manual PAs outlined below will apply to new users.

The P&T Committee recommended the following: (15 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Tresiba, Uloric, Nuplazid, and Hemlibra; and updates to the manual PA criteria and step therapy for the TIBs, and recommended (14 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Dupixent.

The updates are as follows:

1. **Basal Insulins: Insulin degludec (Tresiba)—**The basal insulin drug class was reviewed for formulary placement in August 2017. Insulin glargine (Lantus) is now the step-preferred basal insulin and is required before use of other products. Insulin glargine 300 U/mL (Toujeo) is UF and non-step-preferred. The NF, non-step-preferred basal insulins include insulin degludec (Tresiba). The PA criteria for new users of Tresiba were updated to encourage use of the formulary cost-effective basal insulins, prior to use of non-formulary less cost-effective agents.

2. **Corticosteroids – Immune Modulators – Atopic Dermatitis Subclass: dupilumab (Dupixent)—**Dupixent was most recently reviewed for formulary placement at the August 2018 DoD P&T Committee meeting. Manual PA criteria have been in place since May 2017. In October 2018, the FDA granted Dupixent an additional indication as maintenance treatment in patients with moderate to severe asthma aged 12 years and older. The PA criteria were updated to match the additional FDA indication.

3. **Anti-Gout Drugs: Febuxostat (Uloric)**—Manual PA criteria were previously recommended for febuxostat at the May 2013 P&T Committee meeting. Results from the recent CARES Trial, a large cardiovascular (CV) outcomes trial in patients with gout at risk for major CV events, showed an increased risk for a secondary endpoint of cardiovascular death for Uloric compared to allopurinol. The primary endpoint for the study (a composite of the first occurrence of CV death, nonfatal myocardial infarction, or need for urgent revascularization) showed no difference between Uloric and allopurinol. The Uloric PA criteria were updated to ensure that patients and providers are aware of the results of the trial.

4. **Antipsychotic Agents – Atypical: pimavanserin (Nuplazid)—**Nuplazid was reviewed as a new drug in August 2016 with PA criteria due to safety concerns of the black box warning of the increased risk of death in elderly patients with dementia-related psychosis. The FDA recently raised a new safety concern associating pimavanserin with increased mortality and serious adverse drug events when used in

combination with antipsychotics or other QT-prolonging agents. The P&T Committee updated the Nuplazid PA criteria to include these new safety concerns.

5. **Antihemophilic Factors: emicizumab-kxwh (Hemlibra)—**Hemlibra was reviewed as a new drug in February 2018 with manual PA criteria recommended. In October 2018, the FDA approved Hemlibra in newborns and expanded the treatment population to patients with or without factor VIII inhibitors. The PA criteria were updated to match FDA indications.

6. **Targeted Immunomodulatory Biologics (TIBs)—**The TIBs were most recently reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. Since then, several new products have entered the market, and there are now 17 TIBs available. The P&T Committee reviewed the PA criteria, the step therapy, and MN forms for all the products to ensure they were updated with current or additional FDA-approved indications, safety warnings, and similar formatting.

B. Updated PA Criteria and Step Therapy—PA Implementation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the current PA become effective 30 days after the signing of the minutes for the following drugs: the insulin product Tresiba, the gout drug Uloric, the antipsychotic Nuplazid, and the hemophilia drug Hemlibra; and updates to the manual PA criteria and step therapy for the TIBs.

The P&T Committee also recommended (14 for, 0 opposed, 0 abstained, 2 absent) updates to the current PA for Dupixent become effective 30 days after the signing of the minutes.

IX. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA AND STEP THERAPY

BAP Comments

A. Updated Manual PA Criteria and PA Renewal Criteria

The P&T Committee recommended updates to the current manual PA criteria for the drugs discussed above.

BAP Comment: □ Concur □ Non-concur

B. Updated Manual PA Criteria and PA Renewal Criteria—PA Implementation Plan

The P&T Committee recommended the updates to the PA criteria for the drugs discussed above become effective 30 days after the signing of the minutes.

BAP Comment: □ Concur □ Non-concur

X. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

P&T Comments

A. New PA Criteria

New Manual PA Criteria were recommended for the following drugs, which will be discussed below.

1. **Pain Agents—Non-steroidal Anti-inflammatory Drugs (NSAIDs): diclofenac potassium liquid filled capsules (Zipsor), diclofenac submicronized (Zorvolex), indomethacin submicronized (Tivorbex), naproxen CR (controlled-release) (Naprelan/generics), meloxicam submicronized (Vivlodex)—**The NSAIDs were reviewed for UF placement in August 2011, with several generic products designated as UF, including naproxen, diclofenac potassium, diclofenac sodium, indomethacin, and meloxicam.

   Zipsor, Zorvolex, Tivorbex, and Naprelan are branded products that contain the same active ingredients and have the same indications as the generic UF NSAIDs. These branded products lack data showing improved efficacy or safety over the generic NSAIDs and are not cost-effective. Cost-effective generic formulations of naproxen sodium and several other NSAIDs are available on the UF without PA required.

   The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Zipsor, Zorvolex, Tivorbex, naproxen CR (controlled-release) (Naprelan/generics), and Vivlodex due to the significant cost differences and lack of clinically compelling benefits between these products and generic NSAIDs. New and current users of these products are required to try four formulary generic IR NSAIDs, three of which are BCF agents, first.

   Manual PA criteria apply to all new and current users of naproxen CR (Naprelan/generics), Tivorbex, Vivlodex, and Zipsor, and Zorvolex. Coverage will be approved if all a clinical rationale of why the patient cannot take any of the formulary NSAIDs is stated on the PA form.

   Non-FDA-approved uses are NOT approved.
   Prior authorization expires in one year. PA will be renewed for an additional year if a new PA form is completed

2. **Skeletal Muscle Relaxants and Combinations: chlorzoxazone 250 mg tablets—** Generic formulations of the skeletal muscle relaxant chlorzoxazone are available in 250 mg tablets and 500 mg scored tablets. Chlorzoxazone 250 mg tablets are from a single source, while several manufacturers produce the 500 mg tablets. Cost-effective generic formulations of chlorzoxazone and multiple comparable muscle relaxants (e.g., cyclobenzaprine, methocarbamol) are available on the UF without PA required.

   The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new and current users of the single-source chlorzoxazone 250 mg tablets, due to the significant cost differences and lack of clinically compelling benefits compared with administering half of a 500 mg tablet or using other generic muscle relaxants.

   Manual PA Criteria apply to all new and current users of chlorzoxazone 250 mg. Coverage for chlorzoxazone 250 mg tablets will be approved if the provider explains why the patient requires chlorzoxazone 250 mg tablets and why the patient cannot take one-half of a 500 mg tablet. Note that no PA is required for the chlorzoxazone 500 mg tablets.

   Non-FDA-approved uses are NOT approved.
   Prior authorization does not expire.

3. **Oncologic Agents for unresectable or metastatic melanoma: cobimetinib (Cotellic)**—Cobimetinib (Cotellic) was approved for treating unresectable or metastatic melanoma with a specific mutation. It is used exclusively in combinations of a specific BRAF drug with a specific MEK inhibitor, vemurafenib (Zelboraf). Due to the risk of enhanced toxicity if other combinations of BRAF with MEK inhibitors are administered together, the PA criteria were updated to prevent the use of concurrent therapies outside of the FDA-approved combination.

   The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria in new users of Cotellic to ensure it is used only in combination with vemurafenib (Zelboraf).

   Manual PA Criteria apply to all new uses of Cotellic. Coverage will be approved if all the following are met:
   - Age ≥ 18 years
   - Has unresectable metastatic melanoma
   - Has confirmed BRAF V600E or V600K mutation by an FDA-approved test
   - Cotellic is being taken in combination with vemurafenib (Zelboraf)
   - Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), dabrafenib (Tafinlar), nor trametinib (Mekinist)
   - Prescribed by or in consultation with an oncologist

   Non-FDA-approved uses are NOT approved.

Prior authorization does not expire.

4. **Antiinfectives: Miscellaneous: crotamiton 10% lotion (Eurax and Crotan)—**The committee reviewed two treatments for scabies, Eurax and Crotan, which are both crotamiton 10% generic lotions. According to the Centers for Disease Control and Prevention (CDC), first-line treatment for scabies remains permethrin 5% cream (Elimite, others). Permethrin 5% cream is indicated for patients 2 months and older and has a lower failure rate than crotamiton, which is indicated for patients 18 years and older. Cost-effective generic formulations of permethrin cream and oral scabies agents (e.g., ivermectin) are available on the UF without a PA required.

   The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Eurax and Crotan due to concern regarding the limited age range and higher treatment failure rate of these two products, compared to permethrin 5% cream. New users of Crotan or Eurax must document therapeutic failure of permethrin 5% cream first.

   Manual PA criteria apply to all new users of Eurax/Crotan. Coverage will be approved if all criteria are met:

   - Age ≥ 18 years
   - Patient has a diagnosis of scabies caused by *Sarcoptes scabiei*
   - Patient must have tried and failed permethrin 5% in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced

   Non-FDA-approved uses are NOT approved.
   Prior authorization expires in 30 days.

   Renewal of PA is not allowed.

B. New PA Criteria—Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) new PAs for the NSAIDs (Zipsor, Zorvolex, Tivorbex, Vivlodex, Naprelan and naproxen CR generics), chlorzoxazone 250 mg, the oncology drug Cotellic, and the scabies products Eurax and Crotan become effective 90 days after the signing of the minutes**.** DHA will send letters to beneficiaries affected by the new PA requirements for the NSAIDs and chlorzoxazone 250 mg, as new and current users will be subject to the new PA requirements.

XI. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

BAP Comments

A. New Manual PA Criteria

The P&T Committee recommended new PA criteria for the drugs discussed above.

BAP Comment: ☐ Concur ☐ Non-concur

B. New Manual PA Criteria—PA Implementation Plan

The P&T Committee recommended the updates to the PA criteria for the drugs discussed above become effective 90 days after the signing of the minutes.

BAP Comment: ☐ Concur ☐ Non-concur

XII. RE-EVALUATION OF NF GENERICS—ADHD/WAKEFULNESS: STIMULANTS SUBCLASS

P&T Comments

Background—The DHA Pharmacy Operations Division Formulary Management Branch monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed. A formal process is used to reevaluate NF medications where generic equivalents are available.

Attention Deficit Hyperactivity Disorder (ADHD)/wakefulness promoting agents drug class: dexmethylphenidate ER (Focalin XR)—The P&T Committee reviewed the current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per unit, for generic dexmethylphenidate ER (Focalin XR). This product has been designated NF since the original ADHD class review in February 2007 and was reaffirmed at the most recent class review in November 2015. The unit cost of generic formulations of dexmethylphenidate ER has dropped significantly from the previous generic and brand cost.

A. Dexmethylphenidate ER Formulary Status and Implementation

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) returning dexmethylphenidate ER to formulary status, effective the first Wednesday two weeks after the signing of the minutes.

XIII. RE-EVALUATION OF NF GENERICS—ADHD/WAKEFULNESS: STIMULANTS SUBCLASS

BAP Comments

A. Dexmethylphenidate ER Formulary Status and Implementation

The P&T Committee recommended returning dexmethylphenidate ER to formulary status, effective the first Wednesday two weeks after the signing of the minutes.

BAP Comment: □ Concur □ Non-concur

XIV. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

P&T Comments

The P&T Committee reviewed two drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail point of service (POS) and medical necessity at MTFs. These NF drugs will be exempt from movement to the Mail Order POS and will remain available at the Retail POS without pre-authorization due to potential for acute use.

A. Drugs Designated as NF

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) that the Section 703 non-compliant NDCs of the following products be designated NF on the UF:

- Genericus, Inc.: tobramycin inhalation solution pak 300 mg/5 mL ampule-nebulizer
- Genus Lifesciences Pharma: oxycodone hydrochloride solution 5 mg/5 mL oral solution

B. Preauthorization Criteria

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following pre-authorization criteria for the Section 703 non-compliant NDCs of tobramycin inhalation

solution pak and oxycodone hydrochloride solution:

1. Obtaining the product by home delivery would be detrimental to the patient, and
2. For branded products with products with AB-rated generic availability, use of the generic product would be detrimental to the patient.

These pre-authorization criteria do not apply to any other POS other than retail network pharmacies.

B. Implementation Period

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for the Section 703 non-compliant tobramycin inhalation solution pak and oxycodone hydrochloride solution, and 2) DHA send letters to beneficiaries affected by this decision.

XV. SECTION 703 NDAA FY 2008

BAP Comments

A. Drugs Designated NF

The P&T Committee recommended the following two products be designated NF on the UF: tobramycin inhalation solution pak and oxycodone hydrochloride solution.

BAP Comment: ☐ Concur ☐ Non-concur

B. Preauthorization Criteria

The P&T Committee recommended the following pre-authorization criteria for the two Section 703 non-compliant drugs as discussed previously.

BAP Comment: ☐ Concur ☐ Non-concur

C. Implementation Period

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period, and 2) DHA send letters to beneficiaries affected by this decision.

BAP Comment: ☐ Concur ☐ Non-concur

XVI. INFORMATIONAL ITEM—REMOVAL OF BRAND OVER GENERIC AUTHORITY AND PA CRITERIA AUTHORIZATION

P&T Comments

A. Removal of Brand over Generic Authority and Brand over Generic PA Criteria Authorization for Sildenafil Tablets (Viagra)

TRICARE policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, when AB-rated generic formulations for sildenafil (Viagra) were launched in December 2017, pricing for the branded product was significantly lower than the generic formulations. The manufacturer of Viagra offered a Distribution and Pricing Agreement (DAPA) and on January 24, 2018, brand over generic authority was implemented, which allowed for the continued dispensing of the branded product, and required prior authorization prior to dispensing a generic product instead of the brand. Additionally, at that time, the Tier 1 (generic) copayment was assigned to the branded product. The Committee was notified of these actions at the February 2018 DoD P&T Committee meeting, and these recommendations were presented to this Panel at the April 5th BAP meeting.

In May 2016, the P&T Committee recommended the DHA Pharmacy Operations Division (POD) be given authority, after consulting with the Chair of the P&T Committee, to implement "brand over generic" authorization for drugs with recent generic entrants where the branded product is more cost-effective than generic formulations. Authority was also given to the POD to remove the "brand over generic" requirement when it is no longer cost-effective to the MHS.

As of September 2018, the AB-rated generic formulations for sildenafil (Viagra) are cost-effective compared to the branded Viagra product. On September 20, 2018, the brand over generic requirement was removed for sildenafil. The prior authorization criteria remain in effect for the phosphodiesterase-type 5 (PDE-5) inhibitor class as a whole.

XVII. INFORMATIONAL ITEM—REMOVAL OF BRAND OVER GENERIC AUTHORITY AND PA CRITERIA AUTHORIZATION

BAP Comments

A. Removal of Brand over Generic Authority and PA Criteria Authorization for Sildenafil Tablets (Viagra)

BAP Comment:

XVIII. INFORMATIONAL ITEM—DRUGS LOSING RX STATUS AND MOVING TO OTC STATUS

P&T Comments

A. Drugs Losing Rx Status and Moving to OTC Status (Vitamin B Replacement Products, Iron Replacement Products, and Urinary pH Modifiers)

Effective January 1, 2019, any vitamin, dietary supplement or pediatric fluoride product currently listed as requiring a prescription in the First DataBank Database will change to OTC status. The list does not include prenatal vitamins, due to ongoing litigation. OTC pediatric fluoride drops will remain covered. None of the products on the list have been approved by the FDA. The change in status means that, as of January 1, 2019, products on this list will no longer be covered under the TRICARE pharmacy benefit.

The most commonly dispensed categories on the list include vitamin B preparations (various combinations of vitamin B complex and folic acid, along with vitamins D3, C, biotin, zinc, selenium, etc.), iron replacement products (various combinations of iron with folic acid, along with vitamins C, B, B12, calcium, zinc, biotin, docusate sodium, etc.), and urinary pH modifiers (e.g., sodium and/or potassium citrate with citric acid).

The P&T Committee agreed that none of these products are suitable for inclusion on the OTC pharmacy benefit, since they are not FDA-approved. Additionally these products are widely available as either prescription alternatives that would be covered, or low-cost over the counter products. The change will affect beneficiaries across all points of service. Letters are being prepared for delivery to affected beneficiaries.

XIX. INFORMATIONAL ITEM—DRUGS LOSING RX STATUS AND MOVING TO OTC STATUS

BAP Comments

A. Products Losing Prescription Status in First DataBank Recommendation

BAP Comment:

XX. INFORMATIONAL ITEM—TRICARE MAIL ORDER AUTO REFILL REQUIREMENTS

P&T Comments

A. TRICARE Mail Order Auto Refill Requirements for Self-Monitoring Blood Glucose Systems (SMBGS) Test Strips and Lancets

Background—The Committee was briefed on the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy, including opt-in requirements, alert notifications, and auto-refill logic. The SMBGS test strips are in the top ten list of drugs that individual patients request for removal from the program.

The P&T Committee recommended removing the SMBGS test strips and lancets from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy. Reasons for removing the test strips and lancets include the large volume of patient requests for removal; the fact that both test strips and lancets are widely available OTC; the current quantity limits exceed typical usage patterns; overrides to the current quantity limits are available for clinical reasons; and to reduce the potential for wastage, as the test strips do expire. Beneficiary outreach will occur.

XXI. INFORMATIONAL ITEM—TRICARE MAIL ORDER AUTO REFILL REQUIREMENTS

BAP Comments

A. SMBGS Test Strips and Lancets Auto Refill Program Recommendation

BAP Comment:

XXII. INFORMATIONAL ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT

Table of Implementation Status of UF Recommendations/Decisions Summary November 2018

DoD PEC Drug Class	UF Drugs	NF Drugs	Implement Date	Notes and Unique Users Affected
Gastro-intestinal-2 Agents: CIC/IBS-C Subclass and Miscellaneous Subclass	**IBS-C/CIC and IBS-D Subclass** ▪ lubiprostone (Amitiza) ▪ linaclotide (Linzess) ▪ plecanatide (Trulance) **Miscellaneous Subclass** ▪ rifaximin (Xifaxan) ▪ eluxadoline (Viberzi) ▪ alosetron (Lotronex, generic) ▪ nitazoxanide (Alinia) ▪ fidaxomicin (Dificid) ▪ vancomycin oral (generics) ▪ vancomycin solution (Firvanq) ▪ neomycin (generics) ▪ metronidazole (Flagyl, generic)	▪ None	Pending signing of the minutes / 90 days	▪ Eluxadoline (Viberzi) and plecanatide (Trulance) moved from NF to UF ▪ Manual PA currently in place for plecanatide, rifaximin, and eluxadoline. ▪ PA criteria added for linaclotide (Linzess) and lubiprostone (Amitiza) for new and current users ▪ No preferred agent within the CIC/IBS-C subclass ▪ No preferred agent among the IBS-D agents Unique Users Affected for Amitiza and Linzess PA Mail – 12,401 MTF – 7,017 Retail – 7,921 Total – 27,339
Neurological Agents Miscellaneous – Movement Disorders Subclass	▪ deutetrabenazine (Austedo) ▪ tetrabenazine (Xenazine, generics) ▪ valbenazine (Ingrezza)	▪ None	30 days after signing of the minutes	▪ Manual PA criteria applies to all new users for deutetrabenazine (Austedo) and valbenazine (Ingrezza). Unique Users Affected not applicable; current PA requirements

November 2018 Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
NSAIDs Naproxen CR (Naprelan, generics), Tivorbex, Vivlodex, Zipsor, Zorvolex,	36	523	106	912
Skeletal Muscle Relaxants and Combinations Chlorzoxazone 250 mg	0	0	70	70