NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

April 17, 2024

http://www.state.nj.us/humanservices/dmahs/boards/durb/

AGENDA

I. Call to order in accordance with New Jersey Open Public Meeting Act

II. Roll Call

III. Review of meeting transcript for January 24, 2024, meeting

IV. Review of draft meeting summary for January 24, 2024, meeting (pages 3-9)

V. Secretary's report (page 10)

VI. Old Business
- A. Synagis Utilization Report (page 11)
- B. Updated proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor products protocol (pages 12-16)

VII. New Business

- A. Proposed protocol for Ingrezza® (valbenazine) (pages 17-18)
- B. Proposed protocol for Egrifta® (tesamorelin) (pages 19-20)
- C. Proposed addendum to the protocol for Spinal Muscular Atrophy (SMA) products (pages 21-23)
- D. Proposed addendum to the protocol for Direct Acting Antivirals (for hepatitis C) products (pages 24-25)
- E. Proposed addendum to Zurzuvae (zuranolone) protocol (page 26)

VIII. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ MCO 4th Quarter 2023 Prior Authorization Report (page 27)
2. Summary of DURB Action Items (page 28-30)
3. (a) DHS, DHSS and MCO Programs Top Drugs Report/Physicians Administered Drugs (by amount paid and by category)
   (b) Antiviral drugs by amount paid

B. Medication information:
1. Can a Common Diabetes Drug Turn Patients' Urine Into Alcohol? https://www.medpagetoday.com/primarycare/diabetes/108630#:~:text=%22This%20seems%20to%20have%20happened,grape%20juice%20turns%20into%20wine.%22

2. Measles' Deadliest Sequelae

https://www.medpagetoday.com/opinion/parasites-and-plagues/108905?xid=nl_mpt_DHE_2024-02-26&eun=g2076570d0r&utm_source=Sailthru&utm_medium=email&utm_campaign=Daily%20Headlines%20Evening%202024-02-26&utm_term=NL_Daily_DHE_dual-gmail-definition

3. Highly Potent Statin Stands Out for Diabetes, Cataract Risks
https://www.medpagetoday.com/cardiology/prevention/106912

January 24, 2024 DURB Meeting Summary (draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Barberio, Dr. Moynihan, Ms. Olson, Dr. Lind (ex-officio) Unable to attend: Mr. Schafer
Dr. Swee's pre meeting announcement		Dr. Swee called the meeting to order by reading the following statement as required for the first annual meeting of the Board: In compliance with Chapter 231 of the public laws of 1975, notice of this meeting was given by way of the following filings: ✓ On December 18, 2023, it was: • Sent to the local Medical Assistance Customer Centers and County Boards of Social Services to be posted in an area accessible to both employees and the general public • Sent to the Statehouse Press Office • Sent to the offices of Legal Services of New Jersey • Sent to a division of Medical Assistance and Health Services (DMAHS)-which maintains a list of interested parties ✓ It was sent to the following newspapers: the Atlantic City Press, the Bergen Record, the Camden Post, the Newark Star-Ledger, the Trenton Times, and it was published on December 22 or 23 (depending on the newspaper) ✓ On December 27, 2023, it was posted on the DHS/DMAHS website ✓ Published in the January 16, 2024, issue of the NJ Register
Review of Minutes	Approved	Minutes from October 18, 2023, meeting was reviewed and approved. The approved meeting summary will also be posted on the DURB website at: http://nj.gov/humanservices/dmahs/boards/durb/meeting/index.html
Secretary's Report		- The Department is working with the Commissioners to sign off on DURB recommended protocols for, January 2023, and April 2023, July 2023, and October 2023 - The DHS Commissioner's office is reviewing the recommended changes for the reappointment and replacement of DURB members.

		Dr. Swee inquired from Dr. Lind why there is a full year of protocols that were recommended by the Board that are not implemented. Dr. Lind responded that the State is trying to get the approvals in a stepwise order. The January protocol is now with the Commissioner of the Department of Health, but he is not sure what the holdup is.
Old Business		
(A) Calcitonin gene-related peptide (CGRP) inhibitors utilization report (2022 vs. 2023)		The Board reviewed a utilization report for calcitonin gene-related peptide (CGRP) inhibitors products for 3rd quarter 2022 versus 3rd quarter 2023. There was 26% increase in the fee-for-service program and 19% increase in the MCO programs.
(B) Updated Duchenne Muscular Dystrophy products protocol	Recommended	The Board reviewed the updated version of the protocol for Duchenne Muscular Dystrophy products protocol. They had approved the protocol at the October 2023 meeting with suggested changes. The Board recommended approval of the protocol as presented.
(C) Updated Vyjuvek protocol	Recommended	The Board reviewed the updated version of the protocol for Vyjuvek. They had also approved the protocol at the October 2023 meeting with suggested changes. The Board recommended approval of the protocol as presented.
New Business		

(A) Proposed addendum to the protocol for CGRP inhibitors	Recommended	The Board reviewed a proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) antagonists for the treatment of migraines. The change was the addition of Zavzpret (zavegepant), a new product recently approved by the FDA for the treatment of acute migraine. The Board recommended approval of the protocol.
(B) Proposed addendum to the protocol for PCSK9 inhibitors	Recommended	The Board reviewed a proposed addendum to the protocol for the proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors. The changes were as follows: 1. Add a 2022 American College of Cardiology (ACC) expert consensus decision pathway (ECDP) recommended LDL-C threshold for ASCVD patients who are at very high risk for subsequent cardiovascular event 2. Add Leqvio® (inclisiran), a recently approved PCSK9 modifier. 3. Change protocol name to "Protocol for the Safe and Efficient Use of PCSK9 Modifiers" - Dr. Marcus expressed concern over criterion #3 (patient is not pregnant). He suggested modifying it to add a risk benefit consideration for the prescriber as recommended by the American Academy of Cardiology. - Dr. Sam Reveron, with Amgen clarified that this was no absolute contraindication. He also commented on the protocol's definition of major cardiovascular risk. Dr. Swee responded that we will keep the definition as is. - Dr. Reveron requested inserting subsection "C" under criterion #8 that allows PCSK9 inhibitors for "patients on maximally tolerated statin who will required >25% further reduction in LDL. Dr. Swee declined inserting specific numbers but deferred to the Medication Exception Program (MEP) staff to make that determination in consultation with the prescriber. - In the section for criteria for reauthorization, Dr. Reveron requested deletion of the 35% reduction in LDL-C requirement. He also requested that the Board consider changing the 30 days required for LDL-C review to 90 days. The Board accepted the change to 90 days but made no recommendation regarding the 35% reduction in LDL-C. - Ms. Suzanne Shugg, a clinical lipid specialist informed the Board that 90 days follow up was better than 30 days for her patients. The Board agreed with that request. The Board recommended approval of the protocol with the changes.

(C) Proposed update to the protocol for Synagis	Recommended	The Board reviewed a proposed update for the protocol for Synagis (palivizumab), a product used for prophylaxis for respiratory syncytial virus (RSV) in pediatric patients. The original protocol was a holdover from a former vendor, First Health. The changes suggested were: Expanded eligibility for 4 additional classes of patients below, and exclusion for Beyfortus. 1. Impaired ability to clear secretions 2. Cystic fibrosis 3. Severe immunodeficiencies 4. Cardiac transplant Dr. Marcus wanted to know the number of patients that are eligible for treatment. Dr. Lind promised to look into that and inform the Board at a later meeting. Dr. Emenike also indicated that he will be looking at the number of patients treated the previous year to give the Board an idea. The Board recommended approval of the protocol.
(D) Proposed addendum to the protocol for Lumizyme	Recommended	The Board reviewed a proposed addendum to the protocol for Lumizyme (alglucosidase alfa), used in the treatment of Pompe Disease. The changes to the protocol were as follows: 1. Add Nexviazyme® (avalglucosidase alfa) 2. Add new product for the treatment of late-onset Pompe disease [Pombiliti® (cipaglucosidase alfa-atga + Opfolda® (miglustat)] 3. Rename protocol to "Pompe disease products protocol" The Board recommended approval of the protocol.
(E) Proposed protocol for Zurzuvae		The Board reviewed a proposed protocol for Zurzuvae (zuranolone), a product approved for the treatment of postpartum depression (PPD). Dr. Gochfeld expressed concern that a pediatrician would

	Recommended	be doing the screening. Dr. Lind responded that they were included as part of the Bright Futures guidelines. Ms. Olson suggested the addition of psychiatric advanced practice nurses, certified nurse midwives, pediatric nurse practitioners, and pediatric advanced practice nurses. Dr. Swee countered that an "appropriate caregiver" would cover these entities. He also wondered if a 17-year-old mother would be treated. Dr. Emenike responded that the State would remove criterion #1 specifying 18 years and older if that is the recommendation of the Board. Dr. Marcus raised concern that a pediatrician would be prescribing Zurzuvae for the mother. Dr. Swee and Dr. Lind pointed out the difficulty of accessing a psychiatrist in the State. Dr. Paul Isikwe, with Biogen, the manufacturer of the product requested that "AND" in criterion #2 be changed to "OR" to accommodate the definition of PPD. The Board agreed. Ms. Olson suggested that it would be better to use the verbiage "appropriate provider" and "appropriate healthcare provider" for the initial and continuation of therapy requirements respectively. Dr. Lind noted that Ms. Jill Krause made a note on the meeting platform's chat board that supporting the Board's appropriate provider verbiage. The Board voted to recommend the protocol with the suggested changes. Dr. Marcus abstained.
Informational **Highlights/Reports**		

1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor.	The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 3rd quarter 2023 are shown below. Plan / (%) PA Requests of claims / Denial (%) / % w/o NF* FFS / 0.8 / 2 / 2 Aetna / 0.9 / 36 / 13 Amerigroup / 0.8 / 38 / 15 Fidelis Care / 1 / 38 / 12 Horizon / 0.9 / 32 / 12 UHC / 1 / 50 / 17 **NF = Non formulary** Note: WellCare is now Fidelis Care.
2. Summary of DURB Actions/Recommendations		The Board reviewed a summary of their actions from previous meetings (January 2023 thru October 2023). There were no comments.
3. DHS/DHSS/MCO Programs Top Drugs Report		Top drugs report for November 2023 (FFS) and October 2023 (MCOs) was provided for review. Drug expenditures during the reporting period is noted below:

Nested table (within item 1):

Plan	(%) PA Requests of claims	Denial (%)	% w/o NF*
FFS	0.8	2	2
Aetna	0.9	36	13
Amerigroup	0.8	38	15
Fidelis Care	1	38	12
Horizon	0.9	32	12
UHC	1	50	17

<table>
<tr><td></td><td></td><td>
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<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>November 2023</td><td>$11,586,337</td><td>$12,080,484</td></tr>
<tr><td>MCOs</td><td>October 2023</td><td>$119,009,542</td><td>$167,889,068</td></tr>
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<tr><td>4. Medication Information</td><td></td><td>Medical information was provided with links for further reading on the topics below:

1. Benefits of Prior Authorizations

2. Poison control centers see surge in calls about weight-loss drugs

3. Longer Use of ADHD Meds May Boost Heart Risk

4. Burnout, Poor Mental Health on the Rise for Healthcare Workers, CDC Says

5. High Blood Pressure in Babies Linked to Adult Atherosclerosis

6. How Much Pain Is 'Enough' to Prescribe Opioids?

7. Reimbursement to Pharmacists for Generic Drugs by Medicare Part D Sponsors

8. 2024 Medicare Part D Stand-Alone Prescription Drug Plans in New Jersey

Dr. Emenike called the attention of the Board to the article on the benefits of prior authorization. Dr. Swee responded that there are two sides to the argument and referenced legislation to cut back on prior authorization recently signed by the Governor.</td></tr>
<tr><td>Follow-up items:</td><td></td><td>Number of pediatric patients in FFS/MCO treated with RSV prophylaxis medication, Synagis</td></tr>
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April 17, 2024

Secretary's Report:

1. The department is working with the Commissioners to review and sign off on DURB-recommended protocols for:
   - July 2023
   - October 2023
   - January 2024

2. The Commissioners have signed off on the DURB-recommended protocols from January 2023 and April 2023.

3. The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members

4. DURB educational newsletter for Morphine Milligram Equivalents (MME) was distributed in March 2024.

Synagis Utilization Report

Paid claims for Synagis for CYs 2022 & 2023 based on service date, as of 03/14/2024

Recipient counts are unduplicated across all providers

	CY 2022		CY 2023	
FFS OR MCO	**UNDUP RECIPS**	**CLAIMS**	**UNDUP RECIPS**	**CLAIMS**
FFS	8	16	7	8
FFS Subtotals	***8***	***16***	***7***	***8***
Aetna	37	113	30	101
Fidelis Care	19	65	23	63
Horizon	284	930	221	667
United Healthcare	83	312	57	208
WellPoint	40	118	41	112
MCO Subtotals	***459***	***1,538***	***366***	***1,151***
GRAND TOTALS (FFS & MCO)	**463**	**1,554**	**368**	**1,159**

Protocol for the Safe and Efficient Use of PCSK9 (proprotein convertase subtilisin kexin type 9) Modifiers

Approved January 2024

Approved January 2016
Updated July 2020
Updated January 2022

Addendum:

1. Add a 2022 American College of Cardiology (ACC) expert consensus decision pathway (ECDP) recommended LDL-C threshold for ASCVD patients who are at very high risk for subsequent cardiovascular event
2. Add Leqvio® (inclisiran)
3. Change protocol name to "Protocol for the Safe and Efficient Use of PCSK9 (proprotein convertase subtilisin kexin type 9) Modifiers"

Praluent® (alirocumab) is a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor antibody indicated:

- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease; OR
- As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C)
- As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

Repatha® (evolocumab) is a PCSK9 inhibitor antibody indicated:

- To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease; OR
- As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce LDL-C; OR.
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- As an adjunct to other LDL-C-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

Leqvio® (inclisiran) is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA indicated**:**

- As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) who require additional lowering of low-density lipoprotein cholesterol (LDL-C); OR

- As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with clinical atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of low-density lipoprotein cholesterol (LDL-C)

Criteria for Approval:

1. Recent laboratory documentation of LDL must be received and must meet one of the following:
    a. LDL-C ≥ 70 mg/dL for documented ASCVD (Must receive documentation of ASCVD as noted under section C below)
    b. LDL-C ≥ 100 mg/dL for familial hypercholesterolemia without documented ASCVD

    c. LDL-C ⩾ 55 mg/dL for established ASCVD at the highest risk of a subsequent cardiovascular (CV) event. Highest risk is defined as:
        i. Having suffered 2 major adverse cardiovascular events (MACE), e.g., AMI, unstable angina, HF); **OR**
        ii. Having suffered 1 major cardiovascular with at least 2 of the following high-risk conditions present (age >65 years; familial hypercholesterolemia; history of CABG or PCI outside of the major CV event; diabetes; congestive heart failure; hypertension, CKD defined as eGFR 15-59 ml/min; current smoking; elevated LDL-C >100mg/dL despite maximally tolerated statin)

2. Patient must not be receiving another PCSK9 modifier
3. Consider the benefit versus risk for pregnant or nursing patients
4. Medication will be administered by a healthcare professional (Leqvio only)
5. Patient must have a confirmed diagnosis of **one** of the following:

    A. **Homozygous familial hypercholesterolemia (HoFH)**
        a. Patient is 18 years of age or older for Praluent or 10 years of age or older for Repatha; **AND**
        b. The patient must not be receiving lomitapide (Juxtapid®) or mipomersen (Kynamro®) **AND**
        c. For a patient with a diagnosis of HoFH without ASCVD and who has a documented contraindication/intolerance to ezetimibe AND statin therapy, the patient must be using Evolocumab (Repatha) together with another LDL-C lowering therapy (e.g., LDL apheresis).
        d. Documentation (medical records, patient's chart) of genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, or ARH adaptor protein 1/LDLRAP1 gene locus OR
        e. Untreated LDL-C >500 mg/dL or treated LDL-C ≥300 mg/dL with ONE of the following:
            (i) Cutaneous or tendon xanthoma before age 10 **OR**
            (ii) Untreated LDL-C levels consistent with heterozygous FH in both parents (untreated total cholesterol >290 mg/dL or untreated LDL-C >190 mg/dL; **OR**

    B. **Primary Hyperlipidemia, including Heterozygous familial hypercholesterolemia (HeFH)**
        a. Patient is 18 years of age or older for Praluent or Leqvio; OR 10 years of age or older for Repatha; **AND**
        b. Patient has diagnosis of HeFH confirmed by one of the following:
            (i) Genetic testing showing a LDL-receptor mutation, familiar defective Apo-B-100, or a PCSK9 mutation **OR**
            (ii) Pretreatment (prior to any hypercholesterolemia therapy) or highest level on treatment total cholesterol >290 mg/dL (>7.5 mmol/L) AND Tendon xanthomas in patient, patient's first degree relative, or patient's second-degree relative **OR**

(iii) Pretreatment (prior to any hypercholesterolemia therapy) or highest level on treatment LDL-C >190 mg/dL (>4.9 mmol/L) AND Tendon xanthomas in patient, patient's first degree relative, or patient's second-degree relative **OR**

(iv) Patient meets definite FH as determined using the Dutch Lipid Clinic Network criteria by a score of greater than 8 (see table 1); **OR**

C. **Clinical atherosclerotic cardiovascular disease (ASCVD)**
   a. Patient is 18 years of age or older
   b. Patient has a history of ASCVD or cardiovascular event
      (i) Provide documentation (medical records, patient's chart) of the condition/event
      (ii) ASCVD is defined as a diagnosis of ONE of the following:
         1. Acute coronary syndrome
         2. History of myocardial infarction (MI)
         3. History of Stable or unstable angina
         4. History of Coronary or other arterial revascularization (e.g., PTCA, CABG)
         5. History of Stroke
         6. History of Transient ischemic attack (TIA)
         7. Peripheral arterial disease presumed to be of atherosclerotic origin
         8. Findings from CT angiogram or catheterization are consistent with clinical ASCVD; OR
         9. Other documented atherosclerotic diseases such as:
            a. coronary atherosclerosis
            b. renal atherosclerosis
            c. aortic aneurysm secondary to atherosclerosis
            d. carotid plaque (≥ 50% stenosis)

7. The prescriber must plan to continue prescribing ezetimibe (unless the patient has a documented contraindication or intolerance to ezetimibe therapy) and a maximally tolerated statin (unless the patient has a documented contraindication or intolerance to statin therapy) together with the requested PCSK-9 inhibitor.
8. The patient must meet one of the following for ezetimibe (a or b):
   a. Patient is currently on ezetimibe AND has documented adherence to ezetimibe for at least the past 90 continuous days (dates and length of therapy must be provided) **OR**
   b. The patient has a documented contraindication or intolerance to ezetimibe therapy
9. Patient has documented adherence to maximally tolerated statins for a combined total of at least the past 90 continuous days **OR**
   a. Documentation that the patient was not able to tolerate a high-intensity statin, but used a high-intensity statin and decreased the daily dose of statin OR trial of two lower intensity statins
10. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

Initial Approval: Six months

Criteria for Reauthorization:

1. The patient must not be receiving more than one PCSK-9 modifier.

2. For homozygous familial hypercholesterolemia, the patient must not be concurrently receiving lomitapide (Juxtapid) or mipomersen (Kynamro).
3. Consider the benefit versus risk for pregnant or nursing patients
4. The patient has been adherent to and must plan to continue using PCSK-9 inhibitor, maximally tolerated statin, and ezetimibe therapy (unless patient has a contraindication or intolerant to statin and/or ezetimibe therapy) for the past 90 continuous days with documentation provided AND demonstrated by the following:

Subsequent Requests: The patient has experienced at least a 35%* reduction in LDL-C compared to the initial request (laboratory documentation of LDL-C must be received from within 90 days).

Will be approved for 1 year if patient meets criteria

***** *If the patient has HeFH with a baseline LDL-C ≥ 160 mg/dl, patient has experienced at least a 24% reduction in LDL-C compared to the initial request.*

5. For a patient with a diagnosis of HoFH without ASCVD and who has a documented contraindication/intolerance to ezetimibe AND statin therapy, the patient must be using Evolocumab (Repatha) together with another LDL-C lowering therapy (e.g., LDL apheresis).
6. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

Table 1. Dutch Lipid Clinic Network Diagnostic criteria**

Criteria	Points
Family History	
1st degree relative with known premature* coronary and vascular disease, OR 1st degree relative with known LDL-C level above the 95th percentile	1
1st degree relative with tendinous xanthomata and/or arcus cornealis, OR Children aged <18 years old with LDL-C level above the 95th percentile	2
Clinical History	
Patient with premature* coronary artery disease	2
Patient with premature* cerebral or peripheral vascular disease	1
Physical examination	
Tendinous xanthomata	6
Arcus cornealis prior to age 45 years	4
Cholesterol levels mg/dL (mmol/liter)	
LDL-C ≥ 330 mg/dL (≥ 8.5 mmol/L)	8
LDL-C 250-329 mg/dL (6.5-8.4 mmol/L)	5
LDL-C 190-249 mg/dL (5.0-6.4 mmol/L)	3
LDL-C 155-189 mg/dL (4.0-4.9 mmol/L)	1
DNA analysis	
Functional mutation in the LDLR, apo B, or PCSK9 gene	8

*Premature: < 55 years in men; < 60 years in women

** Definite diagnosis based on score of >8.

References:

1. Praluent. Prescribing Information. Sanofi-Aventis. Bridgewater, NJ. 4/2021.
2. Repatha. Prescribing Information. Amgen. Thousand Oaks, CA. 9/2021.
3. Leqvio [package insert]. Novartis Pharmaceuticals Corporation East Hanover, New Jersey. December 2021
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.

5. Alirocumab. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: http://www.clinical pharmacology.com. Updated 8/2018
6. Evolocumab. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: http://www.clinical pharmacology.com. Updated 8/2018
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8. Schwartz GG, Steg PG, Szarek M, et al. Alirocumab and cardiovascular outcomes after acute coronary syndrome. N Engl J Med 2018; 379:2097-2107.
9. Szarek M, White HD, Schwartz GG, et al. Alirocumab Reduces Total Nonfatal Cardiovascular and Fatal Events: The ODYSSEY OUTCOMES Trial. J Am Coll Cardiol 2019;73:387-96.
10. Murphy SA, Pedersen TR, Gaciong ZA, et al. Effect of the PCSK9 Inhibitor Evolocumab on Total Cardiovascular Events in Patients With Cardiovascular Disease: A Prespecified Analysis From the FOURIER Trial. JAMA Cardiol. 2019;4(7):613-619. doi:10.1001/jamacardio.2019.088
11. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically
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13. Ray KK, Troquay RP, et al. Long-term efficacy and safety of inclisiran in patients with high cardiovascular risk and elevated LDL cholesterol (ORION-3): results from the 4-year open-label extension of the ORION-1 trial. Lancet Diabetes & Endocrinology. 2023; 11:109-119
14. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al.; Writing Committee. 2022 ACC expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2022;80:1366-418.
15. Roe MT, Li QH, Bhatt, DL, et al. Categorization Using New American College of Cardiology/American Heart Association Guidelines for Cholesterol Management and Its Relation to Alirocumab Treatment Following Acute Coronary Syndromes. Circulation Volume 140, Issue 19, 5 November 2019; 1578-1589

Proposed Protocol for Ingrezza® (valbenazine)

April 2024

Ingrezza *is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia OR chorea associated with Huntington's disease.*

Tardive dyskinesia *is a syndrome that includes a group of iatrogenic movement disorders caused by the blockade of dopamine receptors. The movement disorders include akathisia, dystonia, buccolingual stereotypy, myoclonus, chorea, tics, and other abnormal involuntary movements, which are commonly caused by the long-term use of typical antipsychotics.*

Chorea *is a neurological disorder characterized by spasmodic involuntary movements of the limbs or facial muscles.*

Criteria for approval:

A. Tardive dyskinesia:

1. Patient has a diagnosis of moderate to severe tardive dyskinesia (TD) confirmed by an Abnormal Movement Scale (AIMS) score of 3 or 4 on any one of the items 1 through 7

2. Diagnosis of TD with symptoms has been present for at least 4 to 8 weeks

3. Medication is prescribed by or in consultation with a neurologist or psychiatrist

4. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

B. Chorea associated with Huntington's disease

1. Patient has a diagnosis of chorea associated with Huntington's disease that is disruptive to functioning

2. Huntington's disease has been confirmed by genetic testing.

3. Should NOT be used in patients with depression, agitation, psychosis

4. Medication is prescribed by or in consultation with a neurologist or psychiatrist

5. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Documentation of positive clinical response to therapy based in change in AIMS for TD.

2. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

References:

1. Ingrezza [prescribing information]. Neurocrine Biosciences, Inc. San Diego, CA 92130. August 2023
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Bhidayasiri R, Fahn S, et al. Evidence-based guideline: Treatment of tardive syndromes. Neurology; July 30, 2013: 81 (5) 463-469. https://doi.org/10.1212/WNL.0b013e31829d86b6
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Proposed Protocol for Egrifta® (tesamorelin)

April 2024

Egrifta *is a growth hormone-releasing factor (GHRF) analog indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.*

Criteria for approval:

1. Patient has a diagnosis of HIV-associated lipodystrophy

2. Patient is currently receiving anti-retroviral therapy

3. Medication is prescribed by, or consultation with an infectious disease specialist, an HIV practitioner, or an endocrinologist

4. Documentation that the following baseline labs, information has been obtained within the last 30-day period and is available:
   a. Hemoglobin A1C
   b. Insulin-like Growth Factor-1 (IGF-1)
   c. Waist circumference

5. Patient has no contraindication to treatment such as:
   a. Active malignancy
   b. Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma
   c. Pregnancy (consider risk)

6. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Patient is responding positively to therapy as evidenced by documentation of decrease in waist circumference, visceral adipose tissue while on therapy.

2. There is no evidence of exacerbation of glucose intolerance and increased IGF-1 levels

3. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Limitations of use:

a. Long-term cardiovascular safety of Egrifta has not been established
b. Not indicated for weight loss management
c. There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta

References:

1. Egrifta [prescribing information]. Theratechnologies Inc., Montréal, Québec, Canada H3A 1T8. July 2019
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Glesby MJ. (2022). Treatment of HIV-associated lipodystrophy. UpToDate. Retrieved February 4, 2023 from https://www.uptodate.com/contents/treatment-of-hiv-associated-lipodystrophy

Proposed Addendum to the Protocol for Spinal Muscular Atrophy (SMA) Products

Updated April 2024

Updated and approved January 2023

Evrysdi (risdiplam)
Spinraza (nusinersen) – Protocol approved August 2017
Zolgensma (onasemnogene abeparvovec) – Protocol approved July 2019

Addendum:
Remove previous criterion #2 which read: Patient has SMA types I, II, or III

Background:
Spinal muscular atrophy (SMA) is characterized by degeneration of the anterior horn cells in the spinal cord and motor nuclei in the lower brainstem, which results in progressive muscle weakness and atrophy.

***Evrysdi** is a small molecule SMN2 splicing modifier that binds two sites in SMN2 pre-messenger RNA, thereby correcting the splicing deficit of SMN2, leading to increased levels of full-length SMN protein.*
***Spinraza** is an antisense oligonucleotide (ASO) that modifies splicing of the SMN2 gene to increase production of normal, full-length survival motor neuron protein, which is deficient in SMA*
***Zolgensma** is a recombinant adeno-associated viral vector containing complementary DNA encoding the normal human survival motor neuron protein (SMN1).*

Criteria for Approval:

1. Patient has a diagnosis of spinal muscular atrophy (SMA)
2. Diagnosis is confirmed by one of the following:
    a. Molecular genetic testing showing homozygous deletions of exon 7 of SMN1; **OR**
    b. Compound heterozygous mutation of SMN1 gene
3. Prescribed by or in consultation with a pediatric/adult neurologist or a physician who is an expert in the treatment of SMA
4. Patient's weight will be monitored
5. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence.

For Evrysdi:

1. Patient will not receive concomitant surviving motor neuron modifying therapy (e.g., Spinraza or Zolgensma)

For Spinraza:

1. Patient will not receive concomitant surviving motor neuron modifying therapy (e.g., Evrysdi or Zolgensma)

2. Lab testing of platelet count to be done at baseline and prior to each dose

For Zolgensma:

1. Patient is less than 2 years of age
2. Patient has bi-allelic mutations in the survival motor neuron (SMN1) gene
3. Patient does not have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence)
4. Baseline anti-AAV9 antibody testing is done, and titers is ≤ 1:50
5. Patient will not receive concomitant surviving motor neuron (SMN) modifying therapy (e.g., Spinraza or Evrysdi)
6. Patient will receive systemic corticosteroid equivalent to oral prednisolone 1mg/kg/day at least 1 day prior to Zolgensma infusion and will continue to receive corticosteroid therapy for at least a total of 30 days (*patient's weight information must be received/documented prior to treatment)*
7. Prescriber attests that patient has not received Zolgensma in their lifetime
8. One dose only will be approved for the treatment of SMA
9. Patient's liver function is assessed prior to administration of Zolgensma and for at least 3 months after infusion

Note: Use of Zolgensma in premature neonates before reaching full-term gestational age is not recommended because concomitant treatment with corticosteroids may adversely affect neurological development.

Continuation of therapy (Evrysdi or Spinraza only):

1. Member will not be receiving more than one surviving motor neuron modifying therapy at a time
2. For Spinraza requests: Lab testing of platelet count will also be done prior to each dose

References:

1. Evrysdi [package insert]. Genentech Inc. South San Francisco, CA 94080; September 2022
2. Spinraza [package insert]. Biogen Inc. Cambridge, MA 02142; June 2020.
3. Zolgensma [package insert] Novartis Gene Therapies, Inc. Bannockburn, IL 60015; August 2022
4. Finkel RS, Kuntz N, Mercuri E, et al. Primary Efficacy and Safety Results from the Phase 3 ENDEAR Study of Nusinersen in Infants Diagnosed with Spinal Muscular Atrophy. Poster presented at: 43rd Annual Congress of the British Paediatric Neurology Association; 11-13 January, 2016; Cambridge, UK.
5. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically.
6. Bodamer OA. Spinal muscular atrophy. In: UpToDate, Dashe JF (Ed). UpToDate, Waltham, MA. (Accessed November 10, 2022)
7. Keinath MC, Prior DE, Prior TW. Spinal Muscular Atrophy: Mutations, Testing, and Clinical Relevance. Appl Clin Genet. 2021 Jan 25;14:11-25.
8. D'Amico, A., Mercuri, E., Tiziano, F.D. et al. Spinal muscular atrophy. Orphanet J Rare Dis 6, 71 (2011).

Protocol for Direct Acting Antiviral Hepatitis C Drugs (Adults)

Updated April 2024

Approved June 2016
Updated and approved October 2017
Updated and approved July 2018
Updated and approved July 2021

Addendum:

1. Remove previous criterion which read: Initial quantity dispensed will be limited to 14 days dosage units (14-14-28-28 format)
2. Delete Viekira Pak
3. Restructure protocol to minimize barriers to access

This protocol covers (but is not limited to) the following medications:

Sovaldi® (sofosbuvir)
Harvoni® (sofosbuvir/ledipasvir)
Zepatier® (elbasvir/grazoprevir)
Epclusa® (sofosbuvir/velpatasvir)
Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)
Mavyret® (glecaprevir/pibrentasvir)

Please refer to individual drug package insert for specific genotypes and other guidelines

Criteria for Approval

A) For Treatment Naïve Patients:

1. Patient is treatment naïve and has a reported diagnosis of hepatitis C **AND**
2. Medication is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

B) For Treatment Experienced Patients:

1. Medication is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
2. Diagnosis of **hepatitis C,** labs showing detectable HCV RNA levels from within the **past 90 days** and genotype must be received, **AND**

3. Provide previous treatment history including medication, length of therapy, and whether the patient is a relapser, null responder, partial responder, or non-compliant.

4. Patient has been educated on the importance of compliance with their treatment regimen.
5. Patient must not have any of the following:
   a. Contraindications to requested Hepatitis C therapy (See PI for complete list)
   b. Patient must not be on any therapies identified by the prescribing information or AASLD/IDSA guidelines as therapies not recommended for co-administration, (see PI and guidelines for complete list)
   c. Limited life expectancy (<12 months due to non-liver related comorbidities). Per AASLD guidelines [2015], HCV therapy would not improve symptoms or prognosis in this patient population and do not require treatment.

6. If combined with ribavirin patient will meet ALL of the following:
   6.1 Patient has no contraindication (See PI for complete list) to ribavirin
   6.2 Neither the patient nor the partner of the patient is pregnant
   6.3 If patient or their partner is of childbearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy.
7. For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist
8. Prescriber attests that patient has been assessed for HBV infection
9. For regimens that depend on testing [e.g., baseline high fold-change NS5A RASs (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), Baseline Q80K polymorphism, Y93H], a copy of the lab work must be received.

References:

1. American Association for the Study of Liver Diseases (AASLD)/Infectious Disease Society of America (IDSA). Recommendations for Testing, Managing, and Treating Hepatitis C. January 29, 2014. Updated on January 21, 2021. Accessed on: May 25, 2021.Available at https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/AASLD-IDSA_HCVGuidance_January_21_2021.pdf. Published Harvoni® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; October 2014.
2. Zepatier® [Prescribing Information]. Merck & Co. Inc., Whitehouse Station, NJ; January 2016.
3. Epclusa® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; June 2016.
4. Vosevi® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; July 2017.
5. Mavyret® [Prescribing Information]. AbbVie Inc., North Chicago, Il 60064: August 2017.

Proposed Addendum to Protocol for Zurzuvae® (zuranolone)

Updated April 2024

Approved January 2024

Zurzuvae *is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults.*

Criteria for approval:

1. Patient has moderate to severe symptoms of postpartum depression; **AND**
2. Patient is ≤ 12 months postpartum; **AND**
3. Medication is prescribed by or in consultation with an appropriate healthcare provider; **AND**
4. Treatment is one time only per pregnancy
5. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

References:

1. Zurzuvae [prescribing information]. Biogen Inc. Cambridge, MA. 02142 August 2023
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Viguera A. Postpartum unipolar major depression: Epidemiology, clinical features, assessment, and diagnosis. In: UpToDate April 2023. Payne J, Lockwood CJ (Eds). Wolters Kluwer. (Accessed on December 8, 2023)
   Liu X, Wang S, Wang G. Prevalence and Risk Factors of Postpartum Depression in Women: A Systematic Review and Meta-analysis. J Clin Nurs. 2022 Oct;31(19-20):2665-2677

NJ DURB Prior Authorization Denial Report - 4th Quarter 2023 (October - December)

	FFS	Aetna	Amerigroup	Fidelis	Horizon	UHC
Total # of Enrolled Beneficiaries	**83,155**	**130,561**	**227,769**	**106,223**	**1,160,482**	**400,510**
Total # of Pharmacy Claims Processed	**441,526**	**544,303**	**1,142,516**	**365,440**	**3,669,223**	**1,030,773**
Total # of Members Requesting Prior Authorization*	**1,458**	**3,452**	**6,356**	**2,436**	**20,659**	**7,258**
Total Prior Authorizations Requests Received**	**3,569 (0.8%)**	**4,480 (0.8%)**	**9,344 (0.8%)**	**3,984 (1.1%)**	**30,783 (0.8%)**	**9,608 (0.9%)**
Received Requests Denials	**68 (2%)**	**1,898 (42%)**	**3,536 (38%)**	**1,330 (33%)**	**9,956 (32%)**	**4,675 (48.7%)**
Without Non-formulary Denials	**68 (2%)**	**745 (16.6%)**	**1,544 (17%)**	**344 (9%)**	**3,505 (11%)**	**1,634 (17.0%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	60 (88%)	643 (34%)	1,272 (36%)	335 (25%)	3,252 (33%)	1,402 (30%)
Excluded Benefit	8 (12%)	102 (5%)	231 (7%)	9 (1%)	253 (3%)	232 (5%)
Non-formulary	0 (0%)	1,153 (61%)	1,992 (56%)	986 (74%)	6,451 (65%)	3,041 (65%)
Other	0 (0%)	0 (0%)	41 (1%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	13.2%	2.3%	3.4%	3.2%	3.2%	3.5%
Antidepressants	4.4%	0.9%	1.6%	0.5%	1.7%	1.2%
Antihypertensives	0.0%	0.5%	0.7%	0.8%	0.6%	0.9%
Antianxiety	0.0%	0.1%	0.2%	0.0%	0.2%	0.1%
Antidiabetics (oral and insulin)	8.8%	13.0%	14.1%	22.5%	23.4%	26.6%
Anticoagulants	0.0%	0.1%	0.0%	0.4%	0.1%	0.3%
Thyroid agents	0.0%	0.4%	0.1%	0.1%	0.3%	0.3%
Ulcer Drugs/Antispasmodics/Anticholinergics	4.4%	2.6%	1.8%	0.8%	1.9%	2.2%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	0.0%	9.7%	6.1%	5.0%	4.2%	2.6%
Antipsychotic/Antimanic agents	1.5%	0.8%	2.0%	0.8%	2.9%	0.6%
Antiasthmatic and Bronchodilator agents	11.8%	6.1%	3.0%	3.8%	6.0%	8.7%
Antivirals (includes both HIV and Hep C)	0.0%	1.2%	0.3%	1.0%	0.5%	0.6%
Digestive Aids (Digestive Enzymes)	0.0%	0.5%	0.3%	0.6%	0.2%	0.0%
Anticonvulsants	0.0%	1.7%	1.0%	2.6%	1.4%	2.7%
Migraine Products	0.0%	3.5%	3.8%	3.2%	5.1%	4.9%
Analgesics Anti-inflammatory	4.4%	2.9%	2.3%	6.5%	1.7%	3.3%
Analgesic Opioids	14.7%	15.8%	6.7%	1.9%	1.5%	1.7%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	1.4%	1.8%	2.2%	1.2%	1.0%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	1.3%	0.4%	0.4%	1.0%	0.4%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.1%	0.1%	0.2%	0.0%	0.0%
Dermatologics (Antipsoriatics-Systemic)	0.0%	15.4%	18.4%	10.1%	13.6%	10.8%

* Value represents unduplicated data and will not include a member more than once, even if multiple requests are made.

** Denominator for percentage is Total Number of Pharmacy Claims Processed.

*** See below for explanation of categories:

Clinical Criteria Not Met: includes categories such as Clinical Criteria Not Met, Drug-Drug Interaction, Therapeutic Duplication, Unacceptable Diagnosis

Excluded Benefit: includes categories such as Duration Exceeded, Excessive Dose, Mandatory Generic

Non-Formulary: includes categories such as Non-Formulary

Other: includes categories such as Directed Intervention, Multiple Pharmacies, Multiple Prescribers, Other DUR related rejections

**** Denominator contains total drug prior authorization requests denied. Breakdown of Therapeutic Drug Classification categories is a sample of prior authorization claims data and is not inclusive of all drug classes. Denial percentages will not equal one hundred percent.

Summary of DURB Recommendations

April 17, 2024

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
January 2024	Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitor products	- The Board recommended the protocol	
	Proposed addendum to the protocol for proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor products	- The Board recommended the protocol with suggested changes to criterion #3 for initial approval and criterion #4 for subsequent requests.	The changes will be presented at the next meeting
	Proposed update to the protocol for Synagis (palivizumab)	- The Board recommended the protocol	
	Proposed addendum to the protocol for Lumizyme (alglucosidase alfa) for Pompe disease	- The Board recommended the protocol	
	Proposed protocol for Zurzuvae (zuranolone)	- The Board recommended the protocol with suggested changes to criteria #1, 2, 4 for initial approval and criterion #2 in continuation of therapy section	The changes will be presented at the next meeting
October 2023	Proposed addendum to biologic receptor modifiers (BRMs) protocol for plaque psoriasis	- The Board recommended the protocol	

	Proposed protocol for Kanuma (sebelipase alfa) Proposed protocol for Vyjuvek (beremagene geperpavec) Proposed addendum to Duchenne muscular dystrophy products protocol	- The Board recommended the protocol - The Board recommended the protocol with suggested changes to criterion #5 - The Board recommended the protocol with suggested changes to criteria # 2, 6 and 10	The updated information was presented at the next meeting The updated information was presented at the next meeting
July 2023	Proposed protocol for Chimeric Antigen Receptor T-cell (CAR T-cell) products Proposed protocol for Qalsody (tofersen) Proposed addendum to the biologic receptor modifiers (BRMs) protocol for plaque psoriasis	- The Board recommended the protocol - The Board recommended the protocol - The Board tabled the protocol pending consult with a dermatologist	
April 2023	Proposed protocol for Skysona® (elivaldogene autotemcel) Proposed protocol for Zynteglo® (betibeglogene autotemcel) Proposed protocol for Hemgenix® (etranacogene dezaparvovec)	- The Board recommended the protocol - The Board recommended the protocol - The Board recommended the protocol - The Board recommended the protocol - The Board recommended the protocol with a suggestion to change criterion #5 to read: Medication is prescribed by or in	

	Proposed protocol for Leqembi® (lecanemab-irmb) Proposed protocol for Livmarli® (maralixibat)	consultation with a hepatologist, gastroenterologist, or other specialist with experience in the treatment of the disease	The updated information was presented at the next meeting