NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

July 19, 2023

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 April 19, 2023, meeting

IV. Review of draft meeting summary for April 19, 2023, meeting (pages 3-7)

V. Secretary's report (page 8)

VI. Old Business
- A. MCO response to PA denials report (pages 9-10)
- B. MCO churn rate request report (page 11)
- C. Utilization report on Leqembi (lecanemab-irmb) and Aduhelm (aducanumab-avwa) [page 12]
- D. Report on non-formulary denials of antidiabetic medications (page 13)
- E. Hemgenix (etranacogene dezaparvovec-drlb) use in pediatric patients (CSL Behring) [page 14]
- F. Calcitonin gene-related peptide (CGRP) inhibitors utilization report (Q1 2022 vs. Q1 2023) [page 15]
- G. Summary of DURB suggested changes to proposed protocol (page 16)
  - Livmarli (maralixibat) see link

VII. New Business
- A. Proposed protocol for Chimeric Antigen Receptor T cells (CAR T-cell) products (pages 17-20)
- B. Proposed protocol for Qalsody (tofersen) [pages 21-22]
- C. Proposed addendum to Biologic Receptor Modifiers (BRMs) for plaque psoriasis protocol (pages 23-25)

VIII. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ MCO 1st Quarter 2023 Prior Authorization Report (page 26)
2. Summary of DURB Action Items (pages 27-28)
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. Weighing the Consequences of Weight-Loss Drugs
   https://www.medpagetoday.com/opinion/second-opinions/104482?xid=nl_secondopinion_2023-05-14&eun=g2076570d0r

2. FDA Approves First Oral Antiviral for Treatment of COVID-19 in Adults
https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-antiviral-treatment-covid-19-adults#:~:text=Today%2C%20the%20U.S.%20Food%20and,19%2C%20including%20hospitalization%20or%20death

3. House Passes Bill to Address Fentanyl Overdoses
https://www.medpagetoday.com/washington-watch/washington-watch/104730?xid=nl_mpt_morningbreak2023-05-30&eun=g2076570d0r&utm_source=Sailthru&utm_medium=email&utm_campaign=MorningBreak_053023&utm_term=NL_Gen_Int_Daily_News_Update_active

4. COVID-19 Vaccines information
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

5. (Board members only). Medication Necessity Forms (MNFs) review for:

a) Skysona (elivaldogene autotemcel)

b) Zynteglo (betibeglogene autotemcel)

April 19, 2023 DURB Meeting Summary (Draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Moynihan, Dr. Barberio, Dr. Lind (ex-officio) Unable to attend: Ms. Olson, Mr. Schafer
Dr. Swee's pre meeting announcement		Dr. Swee called the meeting to order by reading the following statement as required for the Board's meetings: In compliance with Chapter 231 of the public laws of 1975, notice of this meeting was given by way of filings in the Trenton Times, the Star Ledger and Atlantic City Press.
Review of Minutes	Approved	Minutes from January 25, 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 Commissioners have signed off on DURB-recommended protocol for July 2022. - The Department is working with the Commissioners to also sign off on DURB recommended protocols for , April 2022, October 2022, and January 2023. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members. Dr. Swee asked Dr. Lind why there was an out of order approval by the commissioners for July 2022 but not for April 2022's protocol. Dr. Lind responded that the Department had asked the same question but will follow up and have an answer for the Board at the next meeting.
Old Business		
(A)Nobelpharma response regarding Hyftor protocol. Ω		The Board reviewed a response from Nobelpharma, in reference to a question about concomitant use of their product, Hyftor (sirolimus) topical gel with routine vaccination. The Board concluded that due to lack of evidence that topical sirolimus accumulated systemically, there should be no concern about concomitant use with vaccination and therefore do not need the criterion in the protocol.

April 19, 2023 DURB Meeting Summary (Draft)

Issue	Action	Notes
(B) Hyftor proposed protocol	Approved	The Board recommended the protocol.
(C) Rhythm Pharmaceutical's update on Imcivree.		The Board reviewed a response from Rhythm Pharmaceutical's Dr. Heller in reference to Dr. Swee's question on including Hispanics/Latinos when determining BMI used in their studies with the drug Imcivree (setmelanotide). In her report, Dr. Heller cited some studies by the company that included this population.
Summary of DURB suggested change for Gattex (teduglutide) protocol		At the last meeting, the Board suggested deleting the word "adult" in the background section of the Gattex protocol. This change was made and presented as follow up to the Board.
New Business		
(A) Proposed protocol for Skysona	Approved	The Board reviewed a proposed protocol for Skysona (elivaldogene autotemcel), a product used to slow the progression of neurology dysfunction in patients with early, active cerebral adrenoleukodystrophy (CALD). Dr. Marcus wanted to know how the State would confirm the capabilities of the sites where the product will be used and if they will comply with the protocol. Dr. Emenike informed him that prescribers are required to complete a medication necessity form (MNF) prior to use. These forms when completed are attestation that they are meeting the protocol requirements. Dr. Marcus suggested that the MNF should be shared with the Board for their input. The Board recommended the protocol
(B) Proposed protocol for Zynteglo	Approved	The Board reviewed a proposed protocol for Zynteglo (betibeglogene autotemcel), a product used for the treatment of patients with beta-thalassemia who require regular red blood cell transfusions. They also requested to review the MNF for this product. The Board recommended the protocol.
(C) Proposed protocol for Hemgenix	Approved	The Board reviewed a proposed protocol for Hemgenix (etranacogene dezaparvovec), a product used for the treatment of adults with hemophilia B. The Board was concerned that the treatment was not extended to patients under the age of 18. The product's package insert however states that "the safety and

Issue	Action	Notes
		efficacy of Hemgenix in pediatric patients have not been established". The Board requested a follow up with CSL Behring or NJ American Academy of Pediatrics to provide information on how the product could be used for a younger population. Dr. Lind suggested that the drug company may provide information on ongoing studies on pediatric patients aimed at expanding the coverage in the future. The Board recommended the protocol.
(D) Proposed protocol for Leqembi	Approved	The Board reviewed a proposed Leqembi (lecanemab-irmb), a product used for the treatment of Alzheimer's disease. Dr. Gochfeld expressed concern about the product because there is evidence that, it not only may not work, but also could cause harm. She suggested that the highest possible barriers be set for use of the product. Dr. Swee acknowledged her concern but felt there will not be lots of patients eligible for the product because the barriers are already there. Dr. Moynihan informed the Board that as a monoclonal, CMS has an NCD (National Coverage Determination) 200.3, which requires the patient to be in a CMS-approved study to be eligible for treatment. Dr. Swee requested a report on utilization of Leqembi in three months. The Board recommended the protocol. Dr. Gochfeld objected.
(E) Proposed protocol for Livmarli	Approved	The Board reviewed a proposed protocol for Livmarli (maralixibat), a product used for the treatment of cholestatic pruritus in patients with Alagille syndrome. Dr. Marcus was concerned that a pediatrician was not listed as eligible prescriber or consultant for a product indicated for 3 months and older patients. Dr. Lind pointed out that the criterion says, "in consultation with", which means that a pediatrician could prescribe in consultation with a hepatologist, gastroenterologist, or a specialist in Alagille syndrome. After discussion, the Board agreed to amend the criterion to read: "Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or other specialist with experience in the treatment of the disease". The Board recommended the protocol pending the change and presentation of the updated version at the next meeting.

April 19, 2023 DURB Meeting Summary (Draft)

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>Informational Highlights/Reports</td><td></td><td></td></tr>
<tr><td>1. Fee-for-Service/MCO Prior Authorization Report

2. Summary of DURB Actions/Recommendations</td><td>Continue to monitor.</td><td>The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 4th quarter 2022 are shown below.
<table>
<tr><th>Plan</th><th>(%) PA Requests of claims</th><th>Denial (%)</th><th>% w/o NF*</th></tr>
<tr><td>FFS</td><td>0.6</td><td>8</td><td>8</td></tr>
<tr><td>Aetna</td><td>0.7</td><td>39</td><td>12</td></tr>
<tr><td>Amerigroup</td><td>0.8</td><td>36</td><td>14</td></tr>
<tr><td>Horizon</td><td>0.7</td><td>34</td><td>12</td></tr>
<tr><td>UHC</td><td>0.7</td><td>44</td><td>17</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>30</td><td>9</td></tr>
</table>
NF = Non formulary
Dr. Swee expressed concern that United Healthcare's (UHC) denial rate was higher than the other plans. Ms. Kripalani, the Pharmacy Director for UHC informed the Board that as a ratio of total claims processed, UHC's has the lowest denial rate. She also said that her team is working to reduce the total prior authorization burden on prescribers.
Dr. Marcus pointed out the high rate of denials of antidiabetics. Dr. Emenike responded that the denials in that category may be more related to non-formulary products but not necessarily antidiabetics in general. The Board requested a report on denials of this category for the next meeting.

The Board reviewed a summary of their actions from previous meetings (April 2022 thru January 2023).
There were no comments.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for January 2023 (FFS) and December 2022 (MCOs) was provided for review.
Dr. Swee referred to the cost, ranking of insulin in the report while reminding the State of their promise that this cost will go down because of the Inflation Reduction Act. Dr. Emenike pointed out that pricing related to the IRA was</td></tr>
</table>

April 19, 2023 DURB Meeting Summary (Draft)

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<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td></td><td></td><td>implemented in January, 2023 but the report being reviewed although ran in January was from December 2022.

Drug expenditure during the reporting period is noted below:

<table>
<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>January 2023</td><td>$15,001,393</td><td>$15,460,557</td></tr>
<tr><td>MCOs</td><td>December 2022</td><td>$112,278,270</td><td>$158,134,726</td></tr>
</table>
</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided links for reference and further reading.
1. Effect of Higher-Dose Ivermectin for 6 Days vs Placebo on Time to Sustained Recovery in Outpatients With COVID-19
2.The Ethics of Clinical Research Managing Persistent Uncertainty
3. Are High Costs of Newer Diabetes Drugs Deterring Eligible Patients?
4. Docs Push Ivermectin for Flu
5. COVID-19 Vaccines information</td></tr>
<tr><td>Follow-up items:</td><td></td><td>A. Dr. Lind will verify and inform the Board the reason for out of order approvals of the recommended protocols by the Commissioners
B. Provide medication necessity forms (MNF) for Skysona and Zynteglo for board review
C. Obtain information from CSL Behring, the manufacturer of Hemgenix and/or NJ Pediatric Association on how to make use of the product in a younger population
D. Provide a report on Leqembi utilization at the next meeting
E. Provide a report on non-formulary denials of antidiabetic products</td></tr>
</table>

7

NEW JERSEY DRUG UTILIZATION REVIEW BOARD

July 19, 2023

Secretary's Report:

1. The Commissioners have signed off on DURB-recommended protocols for April 2022 and October 2022.

2. The department is working with the Commissioners to review and sign off on DURB-recommended protocols for:
   - January 2023
   - April 2023

3. The DHS Commissioner's office is in contact with NJ PHARMA regarding potential replacement of a board member and we are awaiting information on the appointee.

4. At the last meeting, the Board requested the FFS medical necessity forms for Skysona (elivaldogene autotemcel) and Zynteglo (betibeglogene autotemcel). This information has been shared with the Board members for their review.

MCO Collaborative response

Supplementing the Quarterly DUR denials report: -

Background: -

- Each MCO manages the pharmacy benefit through a formulary developed by a P&T committee and these formulary files are submitted to DMAHS quarterly, and any revisions are reviewed by DMAHS.
- Per 1927(d)(5) of the SSA each plan has an exception process available to request a drug not listed on the formulary and all prior approval process are DMAHS reviewed and approved
- Each MCO provides quarterly to DMAHS the PA denial report. This includes all Prior auth requests received during that quarter in the DMAHS provided template
- The board has expressed concerns on MCO denials, and we have each looked further into our processes to ensure that we are following approved policies and criteria for the formulary requests.
    - The two questions as requested by Zankhana as additional info to respond to the board are included in the table below.

Q4 2022 data	Aetna	Amerigroup	Horizon	UHC	WellCare
Total PA requests received	4,294	8,742	26,414	7,280	2,099
Received requests denied (only formulary denials)	461	1,056	3278	1205	642
Denied PA re-reviewed and approved (either PA or appeals in within 6 months)	110	236	627	278	301
1- What percentage of PA requests (for denied claims) are eventually approved for the initial drug?	23.4%	22.35%	19.1%	23%	24.41%
2- Once all necessary information is received by MCO – how long is the turnaround time for approval (q4 2021 data)	6.15 hours	5.33 hours	3.8 hours	3.3 hours	8.55 hours

Summary of the data review process for these responses-

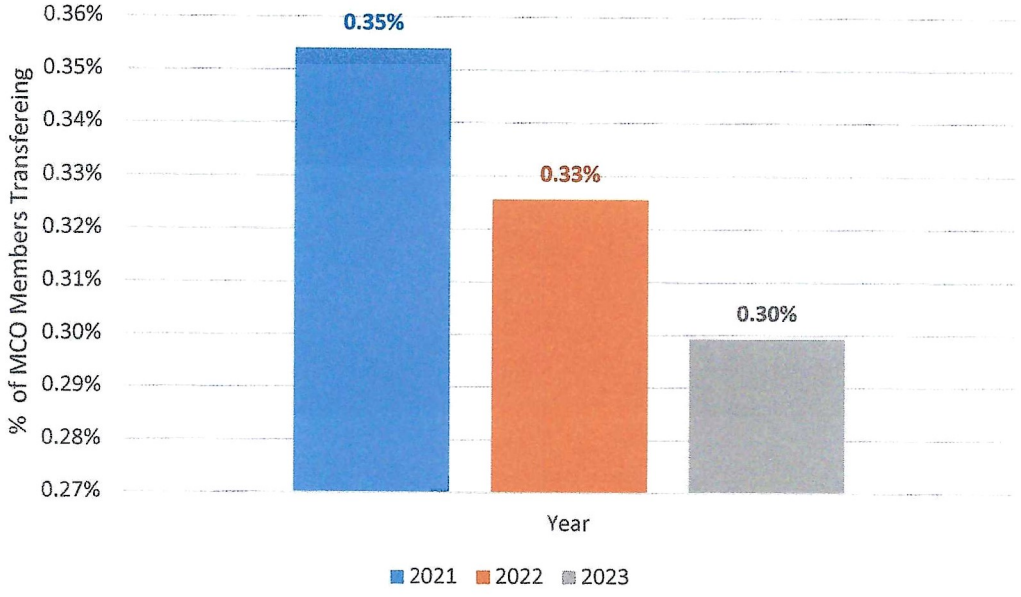
1. All of us collaborated on this approach to ensure we were giving the board similar data to review and for consistency across all plans we have shared data from Q4 2022. We looked at all denials in Q4 for formulary drugs and then looked to see how many of these were approved either via a P2P, subsequent PA or an appeal within that same quarter and the next quarter (Q4 22 and Q1 23).

2. For the average TAT, we used the same quarter Q4 2022, and this is the actual number of hours from the time we receive all the information on a case to review to the time of decision and notification to providers and members.

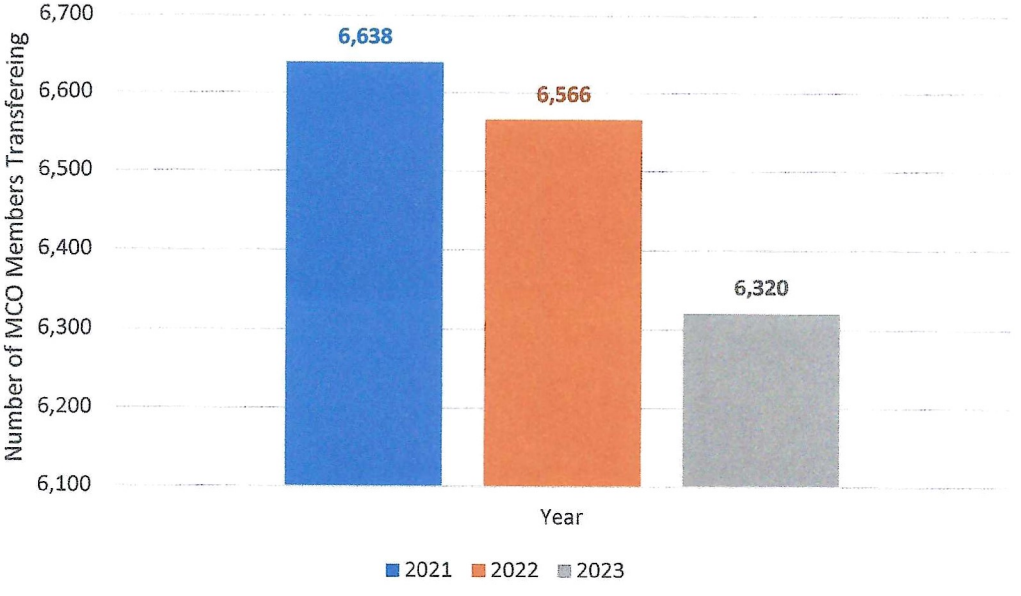
MCO Churn Rate Report (Monthly Average)

July 2023

Average Monthly NJ Medicaid MCO Churn Rate Trend 2021-2023 YTD



Average Monthly NJ Medicaid MCO Churn Rate Trend 2021-2023 YTD



Leqembi (lecanemab-irmb) and Aduhelm (aducanumab-avwa) Utilization Report for 2022 thru June 2023

July 2023

There were no claims for these products during this reporting period.

Denials by Therapeutic Drug Classification (Antidiabetics)
4th Quarter 2022 Denials PA Denials Report

July 2023

The board expressed concerns at the April 2023 DURB meeting regarding the percentages of antidiabetics denied by the MCOs. Those percentages are included at the top row of the table below.

In response to these concerns the State requested of the MCOs to clarify what percentage of denied diabetes medications are due to being non-formulary. That data was used to breakdown the total denials to determine the reason for denial: a denial due to non-formulary status or a denial for other clinical reason. The State receives quarterly formulary updates from each of the MCOs.

Antidiabetic (insulin and other diabetic medications) Denials					
Category	Aetna	Amerigroup	Horizon	UHC	WellCare
% of antidiabetic denials	10%	8.5%	19.6%	17.2%	18.4%
% of antidiabetics denied due to non-formulary status	5%	6%	14%	13%	12%
% of antidiabetics denied for clinical reasons unrelated to formulary status	5%	2.5%	5.6%	4.2%	6.4%

1020 First Avenue
King of Prussia, PA 19406
medinfona@cslbehring.com
800-504-5434 option #1

CSL Behring

20 June 2023

CASE-048953

Sam Emenike
5615 High Point Dr
Irving Texas
75038-2453
United States

Dear Sam Emenike,

Thank you for your request regarding Hemgenix®. The enclosed response contains information on the following topic:

Response Documents:

- HGX_Prescribing Information (v4.0)

No studies have been planned or conducted on the use of Hemgenix in pediatric populations. Consequently, there are currently no established guidelines or protocols available for its administration or usage in children.

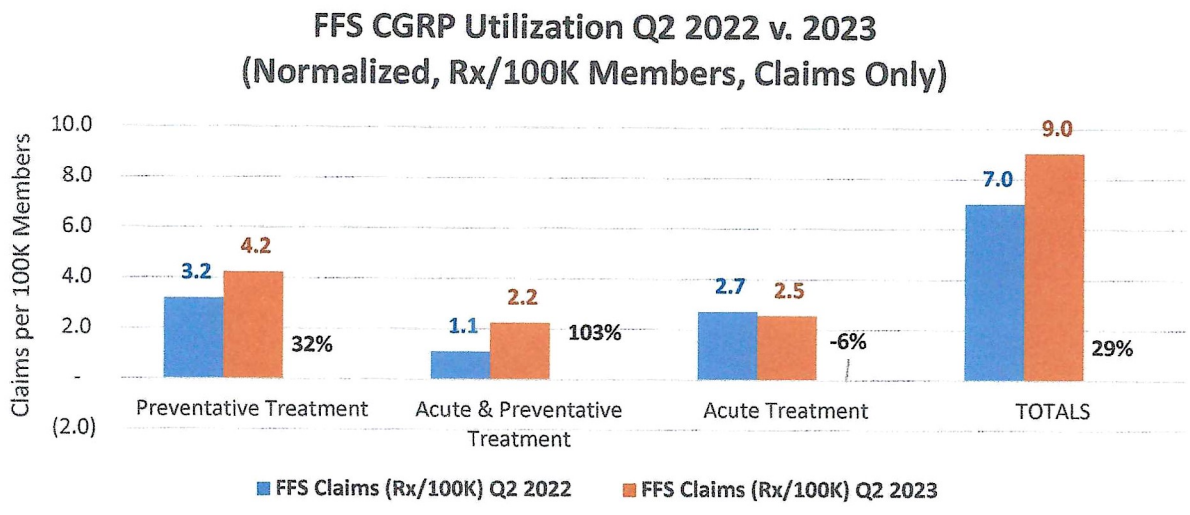
This information is provided in response to your inquiry. CSL Behring recommends the use of its products only as indicated. Please refer to the attached product prescribing information for complete details. If you require further assistance, please contact CSL Behring Medical Information at 800-504-5434.

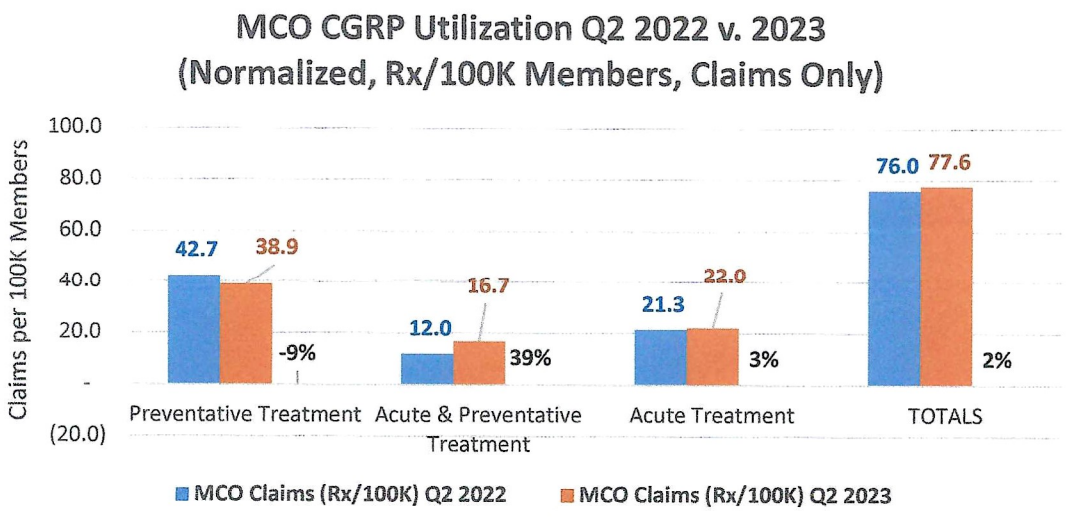
Sincerely,

Monica Nguyen, PharmD
Medical Information Specialist

Calcitonin Gene-Related Peptide (CGRP) Inhibitors Utilization Report (as of 7-10-23)

July 2023





Summary of Board-Suggested Changes to Proposed Protocol

April 2023

Livmarli (maralixibat): The Board recommended rewording criterion #5 to read: "Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or other specialist with experience in the treatment of the disease". See link to updated protocol.

Proposed Protocol for Chimeric Antigen Receptor (CAR) T-cell Products

July 2023

Products:

Abecma® (idecabtagene vicleucel)
Breyanzi® (lisocabtagene maraleucel)
Carvykti® (ciltacabtagene autoleucel)
Kymriah® (tisagenleleucel)
Tecartus® (brexucabtagene autoleucel)
Yescarta® (axicabtagene ciloleucel)

Background: *Chimeric Antigen Receptor (CAR)-T cell therapy is a targeted, personalized therapy that contains patients' autologous T cells reengineered to fight cancer. T cell therapy is approved by the Food and Drug Administration (FDA) to treat certain types of leukemia, lymphoma, and most recently, myeloma.*

Criteria for approval:

1. Medication is prescribed by or in consultation with an oncologist, hematologist, or other specialist in the treatment of the specified disease; **AND**

2. Diagnosis has been confirmed using appropriate tests e.g., histology for Non-Hodgkin Lymphoma (NHL); immunophenotyping for Acute lymphocytic leukemia (ALL), etc., prior to initiating therapy

3. Patient is not currently pregnant; **AND**

4. Patient has no previous history of CAR-T cell therapy; **AND**

5. Patient has no active infections or inflammatory disorders

6. The treating facility is certified under the Risk Evaluation and Mitigation Strategy (REMS) System program appropriate for the requested CAR-T product.

7. Patient is educated on possible drug specific severe adverse reactions with treatment like Cytokine Release Syndrome (CRS), neurologic toxicities, etc.

8. Treatment is one time

9. 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

17

For Abecma:

a. Patient is 18 years or older or age is appropriate based on National Comprehensive Cancer Network (NCCN) compendium 2B or better off-label recommendation; **AND**
b. The request meets one of the following:
    a. Documented diagnosis of relapsed or refractory multiple myeloma; **AND** Documentation of four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody **OR**
    b. Request meets NCCN compendium 2B or better off-label recommendations

For Breyanzi:

a. Patient is 18 years or older or age is appropriate based on NCCN compendium 2B or better off-label recommendation; **AND**
    a. Documented diagnosis of large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:
        i. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first line chemoimmunotherapy; or
        ii. Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or
        iii. Relapsed or refractory disease after two or more lines of systemic therapy **OR**
    b. Request meets NCCN compendium 2B or better off-label recommendations

For Carvykti:

a. Patient is 18 years or older or age is appropriate based on NCCN compendium 2B or better off-label recommendation; **AND**
b. The request meets one of the following:
    a. Documented diagnosis of relapsed or refractory multiple myeloma; **AND** Documentation of four or more prior lines of therapy, including and immunomodulatory agent, a proteasome inhibitor, and anti-CD38 monoclonal antibody **OR**
    b. Request meets NCCN compendium 2B or better off-label recommendations

For Kymriah:

a. The request meets one of the following:
    a. Patient is up to 25 years old with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse **OR**
    b. Patient is 18 years or older with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma **OR**
    c. Patient is 18 years or older with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.
    d. Request meets NCCN compendium 2B or better off-label recommendations

For Tecartus:

a. Patient is 18 years or older or age is appropriate based on NCCN compendium 2B or better off-label recommendation; **AND**
b. The request meets one of the following:
    a. Documented diagnosis of relapsed or refractory mantle cell lymphoma (MCL) **OR**
    b. Documented diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) **OR**
    c. Request meets NCCN compendium 2B or better off-label recommendations

For Yescarta:

a. Patient is 18 years or older or age is appropriate based on NCCN compendium 2B or better off-label recommendation; **AND**
b. The request meets one of the following:
    a. Patient has large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy **OR**
    b. Patient has any of the following diagnosis that has not responded to or have relapsed following two or more lines of systemic therapy:
        i. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
        ii. Primary mediastinal large B-cell lymphoma
        iii. High grade B-cell lymphoma
        iv. DLBCL arising from follicular lymphoma **OR**
    c. Patient has relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy **OR**
    d. Request meets NCCN compendium 2B or better off-label recommendations

References:

1. Abecma [package insert]. Bristol-Myers Squibb Company. Summit, NJ. March 2021
2. Carvykti [package insert]. Janssen Biotech, Inc. Horsham, PA. February 2023
3. Kymriah [package insert]. Norvatis Pharmaceuticals Corp. East Hanover, NJ. May 2022
4. Tecartus [package insert]. Kite Pharma, Inc. Santa Monica, CA. October 2021
5. Yescarta [package insert]. Kite Pharma, Inc. Santa Monica, CA. November 2022
6. Hayden PJ, Roddie C, Bader P, et al. Management of adults and children receiving CAR T-cell therapy: 2021 best practice recommendations of the European Society for Blood and Marrow Transplantation (EBMT) and the Joint Accreditation Committee of ISCT and EBMT (JACIE) and the European Haematology Association (EHA). Annals of Oncology, Vol 33, (3) P259-275, March 2022
7. National Cancer Institute. CAR T-Cells: Engineering Patients' Immune Cells to Treat Their Cancers. March 10, 2022. Accessed online: May 5, 2023. https://www.cancer.gov/about-cancer/treatment/research/car-t-cells
8. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2021. Updated periodically
9. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: multiple myeloma. Version 3.2023. 12/8/2022. [109 screens] https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf

10. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: b-cell lymphomas. Version 4.2023. 6/2/23. [324 screens] https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
11. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: pediatric aggressive mature b-cell lymphomas. Version 1.2023. 4/4/23. [70 screens] https://www.nccn.org/professionals/physician_gls/pdf/ped_b-cell.pdf
12. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: pediatric aggressive mature b-cell lymphomas. Version 2.2023. 3/10/2023. [130 screens] https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf
13. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: pediatric aggressive mature b-cell lymphomas. Version 1.2023. 3/31/2023. [145 screens] https://www.nccn.org/professionals/physician_gls/pdf/all.pdf

Proposed Protocol for Qalsody® (tofersen)

July 2023

Background: *Amyotrophic lateral sclerosis (ALS) is a relentlessly progressive, presently incurable neurodegenerative disorder that causes muscle weakness, disability, and eventually death.*

Qalsody *is an antisense oligonucleotide indicated for the treatment of ALS in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene.*

Note: This indication is approved under accelerated approval based on reduction in plasma neurofilament light (NfL) chain observed in patients treated with Qalsody. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Criteria for approval:

1. Patient is 18 years of age or older; **AND**

2. Patient has a diagnosis of ALS; **AND**

3. Patient has weakness attributable to ALS and has a confirmed mutation in the superoxide dismutase 1 (SOD1) gene **AND**

4. Other motor disorders have been ruled out [e.g., dementia, schizophrenia, and other neurodegenerative diseases such as primary lateral sclerosis (PLS)]

5. Medication is prescribed by or in consultation with a neurologist, neuromuscular specialist, or a physician who specializes in the treatment of ALS **AND**

6. Baseline plasma neurofilament light chain (NfL) levels have been measured **AND**

7. 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. Compared to baseline, there are reductions in plasma neurofilament light chains (NfL) **AND**

2. Prescriber attests to continued monitoring of NfL **AND**

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

21

References:

1. Qalsody [prescribing information]. Biogen MA Inc. Cambridge, MA 02142. April 2023
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Miller TM, Cudkowicz ME, Genge A, et al; VALOR and OLE Working Group. Trial of antisense oligonucleotide tofersen for SOD1 ALS. N Engl J Med. 2022;387(12):1099-1110. doi:10.1056/NEJMoa2204705
4. National Organization for Rare Disorders. Amyotrophic Lateral Sclerosis. Accessed May 5, 2023 at https://rarediseases.org/rare-diseases/amyotrophic-lateral-sclerosis/

Addendum to the Protocol for Biological Response Modifiers in the Treatment of Plaque Psoriasis

July 2023

Approved July 2021

Addendum:

- **Addition of new product, Sotyktu® (approved September 2022)**
- **Add mild Plaque Psoriasis for Otezla (approved December 2021)**
- **Add Enbrel for ≥ 4 years old (per PI)**
- **Add Humira for ≥ 4 years old (Per 2020 American Academy of Dermatology psoriasis in pediatric patients guidelines)**
- **Add FDA approved biosimilars of above products**

Amjevita (adalimumab-atto)
Avsola (infliximab)
Cimzia (certolizumab)
Cosentyx (secukinumab) [≥ 6 years old]
Enbrel (etanercept) [≥ 4 years old]
Humira (adalimumab) [≥ 4 years old]
Ilumya (tildrakizumab)
Inflectra (infliximab)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab)
Siliq (bradalumab)
Skyrizi (risankizimab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab) [≥ 6 years old]
Taltz (ixekizumab) [≥ 6 years old]
Tremfya (guselkumab)

Background:
Biologic response modifiers (BRMs), also known as immunomodulators, are the class of medications that target the disease-causing mechanism. They are used in autoimmune diseases as first-line medications or after the failure of conventional agents. Serious infections are the most severe complications and require screening before initiation, and monitoring while patients are taking the medications.

Criteria for Approval:

A. Patient meets **ALL** the following:

1. <u>For all drugs except Otezla</u>: Diagnosis of moderate to severe plaque psoriasis

2. <u>For Otezla:</u> Diagnosis of plaque psoriasis

23

3. Medication is used for an adult patient except where otherwise indicated

4. Patient must have disease affecting crucial body areas such as hands, feet, face, or genitals OR either a or b:

    a. For all drug requests except Otezla: Patient must have clinical documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 3% body surface involved
    b. For Otezla requests: Patient must have clinical documentation of a diagnosis of mild to severe plaque psoriasis characterized by greater than or equal to 2% body surface involved

5. History of trial and failure of at least **ONE** of the following conventional therapies at maximally tolerated doses (for 3 months) unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):
    i. Methotrexate
    ii. Cyclosporine
    iii. Acitretin
    iv. Topical Vitamin D analogs (e.g., calcitriol)
    v. Topical corticosteroids
    vi. Calcineurin inhibitors (e.g., tacrolimus or pimecrolimus)
    vii. Topical retinoic acid derivatives
    viii. Phototherapy

6. Initial prescription is written by or in consultation with a dermatologist

7. Patient does not have any contraindications to therapy

8. Patient is not receiving medication with another BRM

9. 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

10. Prior to initiation of therapy, patient is tested for tuberculosis (TB) [where applicable]

11. Weight must be received for drugs that have weight-based dosing for any dose change request

Continuation of therapy:

1. Documentation of positive clinical response to therapy

2. Patient is not receiving medication with another BRM

3. Patient is monitored for active TB during treatment (where applicable)

4. Patient is monitored for lymphoma and other malignancies during treatment (where applicable)

Note:
Suicidal ideation and behavior, including completed suicides, have occurred in patients treated with Siliq.

References:

1. Cimzia [packet insert] UCB, Inc. 1950 Lake Park Drive Smyrna, GA 30080. September 2019
2. Cosentyx [packet insert] Novartis Pharmaceuticals Corporation East Hanover, NJ 07936. June 2020
3. Enbrel [packet insert] Amgen. Thousand Oaks, CA 91320. April 2021
4. Humira [packet insert] AbbVie Inc. North Chicago, IL 60064. February 2121
5. Ilumya [packet insert] Merck & Co. Inc., White House Station, NJ 08889. March 2018
6. Otezla [packet insert] Amgen Inc. Thousand Oaks, CA 91320. June 2020
7. Remicade [packet insert] Janssen Biotech, Inc. Horsham, PA 19044. November 2013
8. Skyrizi [packet insert] AbbVie Inc. North Chicago, IL 60064. April 2021
9. Siliq [packet insert] Bausch Health US, LLC Bridgewater, NJ 08807. April 2020
10. Sotyktu [packet insert] Bristol-Myers Squibb Company. Princeton, NJ 08543. September 2022
11. Stelara [packet insert] Janssen Biotech, Inc., Horsham, PA 19044. December 2020
12. Taltz [packet insert] Eli Lilly and Company, Indianapolis, IN 46285. March 2021
13. Tremfya [packet insert] Janssen Biotech, Inc., Horsham, PA 19044. July 2020
14. Menter A et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. A Am Acad Dermatol 2019;80:1029-72
15. Pardasani AG, Feldman SR, Clark AR. Treatment of psoriasis: An algorithm-based approach for primary care physicians. Am Fam Physician 2000;61(3):725-733.
16. Clinical Pharmacology (online database). Tampa FL: Gold Standard Inc.: 2019. Updated periodically
17. Feldman SR. Treatment of psoriasis in adults. UpToDate February 2021. Accessed online 5.3.21 @ https://www.uptodate.com/contents/treatment-of-psoriasis-in-adults
18. Kim WB. Diagnosis and management of psoriasis. Can Fam Physician. 2017 Apr; 63(4): 278–285
19. Wu, JJ. Contemporary Management of Moderate to Severe Psoriasis. Am J Manag Care. 2017;23:S403-S416
20. Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology – National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. J Am Acad Dermatol. January 2020;82:161-201.

25

NJ DURB Prior Authorization Denial Report - 1st Quarter 2023 (January - March)

	FFS	Aetna	Amerigroup	Horizon	UHC	Wellcare
Total # of Enrolled Beneficiaries	**88,769**	**139,853**	**251,331**	**1,212,350**	**427,401**	**111,432**
Total # of Pharmacy Claims Processed	**451,401**	**490,481**	**1,078,384**	**3,850,429**	**1,077,551**	**431,109**
Total # of Members Requesting Prior Authorization*	**1,257**	**3,476**	**7,069**	**21,179**	**7,928**	**2,428**
Total Prior Authorizations Requests Received**	**2,828 (0.6%)**	**4,964 (1.0%)**	**9,971 (0.9%)**	**30,832 (0.8%)**	**10,348 (1.0%)**	**3,579 (0.8%)**
Received Requests Denials	**198 (7.0%)**	**1,844 (37.1%)**	**3,560 (35.7%)**	**10,976 (35.6%)**	**4,636 (44.8%)**	**1,177 (32.9%)**
Without Non-formulary Denials	**198 (7.0%)**	**657 (13.2%)**	**1,586 (15.9%)**	**3,578 (11.6%)**	**1,698 (16.4%)**	**369 (10.3%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	105 (53%)	611 (33%)	1,257 (35%)	3,349 (31%)	1,427 (31%)	361 (31%)
Excluded Benefit	93 (47%)	46 (0%)	276 (8%)	229 (2%)	271 (6%)	8 (1%)
Non-formulary	0 (0%)	1,187 (64%)	1,974 (55%)	7,398 (67%)	2,938 (63%)	808 (69%)
Other	0 (0%)	0 (0%)	53 (1%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	5.1%	6.2%	2.9%	2.5%	3.9%	1.9%
Antidepressants		1.2%	2.1%	1.8%	1.1%	0.6%
Antihypertensives		0.5%	0.9%	0.6%	1.1%	0.2%
Antianxiety	1.5%	0.2%	0.3%	0.2%	0.2%	0.0%
Antidiabetics (oral and insulin)	3.5%	11.1%	9.0%	22.0%	19.5%	20.1%
Anticoagulants	1.5%	0.1%	0.1%	0.1%	0.4%	0.3%
Thyroid agents		0.1%	0.2%	0.2%	0.4%	0.0%
Ulcer Drugs/Antispasmodics/Anticholinergics	23.7%	3.7%	9.5%	1.8%	2.2%	1.3%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants		10.2%	7.3%	4.6%	4.2%	6.6%
Antipsychotic/Antimanic agents	4.5%	0.6%	2.2%	3.4%	1.6%	1.1%
Antiasthmatic and Bronchodilator agents	6.1%	8.8%	2.7%	6.9%	12.0%	4.7%
Antivirals (includes both HIV and Hep C)		1.0%	0.4%	0.4%	0.9%	1.6%
Digestive Aids (Digestive Enzymes)		0.2%	0.2%	0.1%	0.0%	1.1%
Anticonvulsants	2.0%	3.1%	1.1%	1.4%	2.6%	1.2%
Migraine Products		3.3%	3.5%	3.8%	3.9%	3.3%
Analgesics Anti-inflammatory	3.5%	2.6%	1.5%	1.8%	1.4%	3.1%
Analgesic Opioids		5.7%	4.8%	2.0%	2.1%	3.6%
Endocrine and Metabolic Agents-Misc (Growth Hormone)		1.1%	2.0%	0.9%	1.7%	1.9%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)		1.3%	0.7%	0.8%	0.7%	0.7%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)		0.1%	0.1%	0.0%	0.0%	0.2%
Dermatologics (Antipsoriatics-Systemic)	0.5%	16.6%	15.3%	14.5%	12.1%	10.3%

* 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

July 19, 2023

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
April 2023	Proposed protocol for Skysona® (elivaldogene autotemcel)	- The Board recommended the protocol	
	Proposed protocol for Zynteglo® (betibeglogene autotemcel)	- The Board recommended the protocol	
	Proposed protocol for Hemgenix® (etranacogene dezaparvovec)	- The Board recommended the protocol	
	Proposed protocol for Leqembi® (lecanemab-irmb)	- The Board recommended the protocol	
	Proposed protocol for Livmarli® (maralixibat)	- The Board recommended the protocol with a suggestion to change criterion #5 to read: Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or other specialist with experience in the treatment of the disease	The updated information will be presented at the next meeting
January 2023	Addendum to Spinraza®/Zolgensma® protocols	- The Board recommended the protocol	
	Addendum to Imcivree® (setmelanotide) protocol	- The Board recommended the protocol	
	Addendum to Dupixent® protocol (atopic dermatitis)	- The Board recommended the protocol	
	Proposed protocol for Gattex® (teduglutide)	- The Board recommended the protocol with suggestion to remove the word "adult" in the background section.	The updated information was presented at the next meeting
October 2022	Addendum to calcitonin gene-related peptide (CGRP) receptor antagonist protocol	- The Board recommended the protocol	
	Proposed protocol for glucagon-like peptide-1 receptor agonists for T2D	- The Board recommended the protocol with suggestions to reword criterion #3 and removal of criterion #1 under continuation of therapy	An updated version was presented at the next meeting
	Proposed protocol for biologics in moderate to severe asthma treatment	- The Board recommended the protocol	
	Proposed protocol for Cholbam (cholic acid)	- The Board recommended the protocol with suggestion to remove the monitoring requirement in the "continuation of therapy" section	An updated version was presented at the next meeting
	Proposed protocol for Crysvita (burosumab-twza)	- The Board recommended the protocol	

Summary of DURB Recommendations

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
July 2022	Addendum to calcitonin gene-related peptide (CGRP) receptor antagonist protocol	- The Board tabled the protocol with a suggestion to create a flow chart that will make it easier to understand	
	Proposed protocol for Vuity® (pilocarpine ophthalmic)	- The Board recommended the protocol with a suggestion to add optometrist to criterion #3	An updated version was presented at the next meeting
	Proposed protocol for complement inhibitor products (Soliris®, Empaveli®, Ultomiris®)	- The Board recommended the protocol with a suggestion to follow Advisory Committee on Immunization Practices (ACIP) guidelines for determining vaccination needs for the three products	An updated version was presented at the next meeting
	Proposed protocol for Bylvay® (odevixibat)	- The Board recommended the protocol with a suggestion to add "if able to report" to criterion #3	An updated version was presented at the next meeting