NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

January 19, 2022

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 October 20, 2021 meeting

IV. Review of draft meeting summary for October 20, 2021 meeting (pages 3-7)

V. Secretary's report (page 8)

VI. Old Business
- A. Review of updated PA denials report for ALL plans (page 9)
- B. Review of utilization of drugs/products with DURB-recommended protocols (page 10)
- C. "Dear Prescriber" letter/newsletter on ivermectin (pages 11-12)

VII. New Business
- A. Addendum for PCSK9 Inhibitors protocol (pages 13-17)
- B. Addendum for Spravato® (esketamine) protocol (pages 18-19)
- C. Proposed protocol for Gamifant® (emapalumab-lzsg) [pages 20-21]
- D. Proposed Protocol for Nitisinone products (pages 22-23)
- E. Proposed protocol for Lucemyra® (lofexidine) [page 24]
- F. Proposed protocol for Paxlovid® (nirmatrelvir/ritonavir) [page 25]
- G. Proposed protocol for molnupiravir (page 26)

VIII. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ HMO 3rd Quarter 2021 Prior Authorization Report (page 27)
2. Summary of DURB Action Items (pages 28-29)
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. COVID-19 Vaccines information
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
2. Information for Clinicians on Investigational Therapeutics for Patients with COVID-19
https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html Continuously updated.
3. New Jersey COVID-19 Information Hub (continuously updated)
https://covid19.nj.gov/

4. Know Your Treatment Options for COVID-19 – FDA
https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19

IX. Referenced Materials:

A. Addendum for Duchenne muscular dystrophy products – approved October 2021 (pages 30-32)
B. Protocol for Aduhelm® (aducanumab) – approved October 2021 (pages 33-34)
C. Protocol for Bronchitol® (mannitol) – approved October 2021 (page 35)

October 20, 2021 DURB Meeting Summary (draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Ms. Olson, Dr. Barberio, Dr. Lind (ex-officio) Unable to attend Dr. Moynihan, 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, Star Ledger and Atlantic City Press.
Review of Minutes	Approved	Minutes from July 14, 2021 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		- Protocols recommended by the Board in the October 2020, January, April, and July 2021 meetings are being reviewed by the Commissioners. This also includes the DURB annual report for SFY 2020. - The DHS Commissioner is also reviewing the recommended changes for the reappointment and replacement of members that have left the Board. - The Division has hired a new transcriptionist, Lisa Bradley, for the DURB meetings. - The State's chief pharmacist, Zankhana Desai has been working with the MCOs to update the prior authorization denials report. - The proposed dates for the DURB 2022 meetings are as follows: Wednesday, January 19 Wednesday, April 20 Wednesday, July 13 Wednesday, October 19 - The DURB annual report for SFY 2021 is in the packet for the Board members to review and send suggested changes to the Secretary, Sam Emenike, by November 30, 2021,

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October 20, 2021 DURB Meeting Summary (draft)

Issue	Action	Notes
		- Special thanks to Dr. Lind, Zankhana Desai, Ed Vaccaro, Dave Franks, and Beth Bailey for their help in putting the report together. - On behalf of the Board, Dr. Swee welcomed Ms. Lisa Bradley to the DURB meetings. He also extended his gratitude to Zankhana for her efforts in revising the DUR PA denials report template.
Old Business		
Updated DUR PA denials report		Deferred to January 2022 meeting.
New Business		
(A) Addendum for Duchenne muscular dystrophy drugs	Approved	The Board reviewed a proposed addendum for the protocol for Duchenne muscular dystrophy drugs. Changes: a. Added a new product, Amondys 45® (casimersen) that was FDA-approved in February 2021 b. Changed the name of the protocol to "Duchenne muscular dystrophy products". The Board recommended rewording criterion #6 to read: "patient's kidney function will be evaluated before and during treatment as required by medication's label" The Board recommended the protocol
(B) Proposed protocol for Aduhelm® (aducanumab)	Approved	The Board reviewed a proposed protocol for Aduhelm® (aducanumab) a product indicated for the treatment of Alzheimer's disease. Dr. Gochfeld recommended that the range for the Mini-Mental State Exam (MMSE) should be changed to 24-29 from proposed 24-30. The Board requested explanation from Biogen's liaison, Mr. Tanner Odom, who was at the meeting. He explained that other assessment tools were used in combination with MMSE and it would not be a problem to change it as the Board recommended. The Board recommended the protocol contingent on changing the MMSE range to 24-29.

October 20, 2021 DURB Meeting Summary (draft)

Issue	Action	Notes
(C) Proposed protocol for Bronchitol® (mannitol)	Approved	The Board reviewed a proposed protocol for Bronchitol® (mannitol) indicated as an add-on treatment for cystic fibrosis. Dr. Marcus was concerned about the use of the word "oral" to describe the route of inhalation of bronchodilator required prior to use. Dr. Emenike informed the Board that "oral inhalation" used in the protocol was straight out of the drug label. The Board recommended the protocol contingent on removing the word "oral" to avoid confusion.
(D) Proposed protocol for Imcivree® (setmelanotide)	Approved	The Board reviewed a proposed protocol for Imcivree® (setmelanotide), a product indicated for the treatment of obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency. Dr. Swee wanted to know the prevalence of this disease in New Jersey. Dr. Emenike promised to research that information and bring back to the Board. The Board recommended the protocol.
(E) Proposed protocol for Stromectol® (ivermectin)	Approved	The Board reviewed a proposed exclusion protocol for Stromectol® (ivermectin). Due to increased utilization for possible treatment of COVID-19, which is not approved by the FDA or CDC, the State proposed to limit the quantity to the amount needed for the treatment of approved indications. The Board recommended the exclusion protocol with a request that the State also send out a "Dear Prescriber Letter" alerting providers about the warnings from professional organizations against the use of ivermectin for the treatment of COVID-19 also referred to as SARS-CoV-2 infection. Dr. Gochfeld abstained from the vote.
DURB Annual Report for SFY 2021		The DURB annual report for SFY 2021 was sent earlier to the Board members to review with a request to send suggestions, corrections to the Secretary by November 30, 2021. This would allow enough time for commissioners review, approval, and publication in the NJ Register.

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October 20, 2021 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 State is working with the MCOs to revise the current prior authorization (PA) denial report comparing all MCO plans and FFS. The new report template has been sent to the Board members and will be reviewed at the January 2021 meeting. At the meantime, the Board was presented with data for the quarter using the old template.
The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 2nd quarter 2021 are shown below:

<table>
<tr><td>Plan</td><td>(%) PA Requests of claims</td><td>Denial (%)</td></tr>
<tr><td>FFS</td><td>0.5</td><td>12</td></tr>
<tr><td>Aetna</td><td>0.7</td><td>41</td></tr>
<tr><td>Amerigroup</td><td>0.8</td><td>34</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>42</td></tr>
<tr><td>UHC</td><td>0.9</td><td>48</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>48</td></tr>
</table>

The Board reviewed a summary of actions from previous meetings (October 2020 thru July 2021).
There were no comments.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for August 2021 (FFS)/July 2021 (MCOs) was provided for review. Dr. Marcus commented on charge(s) for vaccine in the physician administered drugs report. Ms. Desai informed him that the charge(s) are only for administration fees. Drug expenditure is noted below.

Reported drug expenditures:
<table>
<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>August 2021</td><td>$9,715,452</td><td>$10,250,129</td></tr>
<tr><td>MCOs</td><td>July 2021</td><td>$95,698,728</td><td>$136,135,289</td></tr>
</table>
</td></tr>
</table>

October 20, 2021 DURB Meeting Summary (draft)

Issue	Action	Notes
4. Medication Information		Medical information was presented which provided links to some COVID-19 guides. Although with similar subjects to previous meetings, these are frequently updated sources: a. COVID-19 Vaccine information b. Information for Clinicians on Investigational Therapeutics for Patients with COVID-19 c. New Jersey COVID-19 Information Hub d. Monoclonal Antibody Therapy for COVID-19 in New Jersey e. Lilly COVID-19 Antibody Therapies Access Update: Limitations of Authorized Use Modified by FDA. A list of states, territories, and U.S. jurisdictions in which bamlanivimab and etesevimab are and are not currently authorized
5. Referenced Materials		Updated protocols returned for Board members review of their suggested changes: A. Addendum for Duchenne muscular dystrophy products – approved October 2021 B. Protocol for Aduhelm® (aducanumab) – approved October 2021 C. Protocol for Bronchitol® (mannitol) – approved October 2021
Follow up items:		A. Review of utilization of drugs/products with DURB-recommended protocols B. Prevalence of obesity due to the genetic conditions proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency in New Jersey C. "Dear Prescriber Letter" on the use of ivermectin

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NEW JERSEY DRUG UTILIZATION REVIEW BOARD

January 19, 2022

Secretary's Report:

1. The Commissioners have signed off on DURB-recommended protocols for:
   - January 2020
   - July 2020
   - January 2021

2. The Commissioners have signed off on the DURB annual report for SFY 2020.

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

4. As of November 24, 2021, there were no claims for Imcivree® (setmelanotide), a product used for the treatment of obesity due to impairment of the melanocortin-4 receptor (MC4R) pathway.

NJ DURB Prior Authorization Denial Report - 3rd Quarter 2021 (July - Sept)

	FFS	Aetna	Amerigroup	Horizon	UHC	Wellcare
Total # of Enrolled Beneficiaries	**62,391**	**119,857**	**240,350**	**1,085,359**	**397,918**	**103,507**
Total # of Pharmacy Claims Processed	**1,228,970**	**241,486**	**1,017,829**	**3,550,272**	**1,015,752**	**361,547**
Total # of Members Requesting Prior Authorization*	**2,676**	**2,823**	**5,576**	**15,215**	**7,072**	**1,708**
Total Prior Authorizations Requests Received**	**5,087 (0.4%)**	**4,094 (1.7%)**	**7,641 (0.8%)**	**21,667 (0.6%)**	**8,817 (0.9%)**	**2,559 (0.7%)**
Received Requests Denials	**309 (6.1%)**	**1,457 (35.6%)**	**2,736 (35.8%)**	**6,881 (31.8%)**	**3,783 (42.9%)**	**933 (36.5%)**
Without Non-formulary Denials	**309 (6.1%)**	**549 (13.4%)**	**1,344 (17.6%)**	**2,550 (11.8%)**	**1,173 (13.3%)**	**226 (8.8%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	163 (52.8%)	424 (29.1%)	1,228 (44.9%)	2,329 (33.8%)	1,001 (26.5%)	184 (19.7%)
Excluded Benefit	146 (47.2%)	58 (4.0%)	102 (3.7%)	221 (3.2%)	171 (4.6%)	2 (0.2%)
Non-formulary	0 (0.0%)	908 (62.3%)	1,392 (50.9%)	4,331 (62.9%)	2,609 (69.0%)	707 (75.8%)
Other	0 (0.0%)	67 (4.6%)	14 (0.5%)	0 (0.0%)	1 (0.0%)	40 (4.3%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	1.9%	5.5%	6.0%	3.4%	5.3%	2.5%
Antidepressants	0.0%	1.8%	0.6%	2.8%	1.1%	0.3%
Antihypertensives	0.0%	0.5%	0.3%	0.9%	3.0%	0.4%
Antianxiety	2.6%	0.1%	0.0%	0.2%	0.1%	0.0%
Antidiabetics (oral and insulin)	1.9%	8.0%	4.1%	14.5%	11.1%	14.7%
Anticoagulants	0.3%	1.7%	0.0%	0.1%	0.2%	0.6%
Thyroid agents	0.0%	0.4%	0.1%	0.2%	0.4%	0.6%
Ulcer Drugs/Antispasmodics/Anticholinergics	31.4%	2.8%	1.8%	2.6%	2.2%	1.6%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	0.0%	9.6%	2.5%	3.2%	2.6%	4.7%
Antipsychotic/Antimanic agents	5.8%	1.4%	0.4%	3.1%	1.6%	1.5%
Antiasthmatic and Bronchodilator agents	2.6%	7.9%	1.9%	7.5%	7.1%	4.3%
Antivirals (includes both HIV and Hep C)	1.9%	1.9%	0.7%	1.3%	1.1%	2.9%
Digestive Aids (Digestive Enzymes)	0.3%	0.3%	0.1%	0.1%	0.0%	0.2%
Anticonvulsants	1.0%	3.6%	0.3%	1.6%	2.7%	2.8%
Migraine Products	0.3%	2.7%	2.7%	3.8%	3.8%	3.9%
Analgesics Anti-inflammatory	1.9%	3.7%	0.6%	1.8%	2.8%	3.8%
Analgesic Opioids	2.6%	3.4%	1.1%	2.9%	2.5%	3.5%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	1.3%	1.3%	1.2%	1.0%	3.0%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	1.4%	0.8%	0.6%	0.3%	0.9%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.1%		0.0%	0.1%	0.0%
Dermatologics (Antipsoriatics-Systemic)	0.0%	13.9%	9.8%	14.3%	18.8%	15.7%

* 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.

2021 Utilization of Drug Products/Protocols Reviewed in 2020, as of 1/3/2022

Totals include FFS & MCOs; MCOs are still submitting claims for December 2021

Drugs/Products	Drugs	Total Claims	Total Qty	Total Undup. Users	Total Pmts	FFS Claims	FFS Qty	FFS Users	FFS Pmts	MCO Claims	MCO Qty	MCO Users	MCO Pmts
Fabry disease products	Fabrazyme	41	278	3	$ 593,682	-		-		41	278	3	$ 593,682
	Galafold	8	112	1	$ 203,336	-		-		8	112	1	$ 203,336
Lambert-Eaton Myasthenic Syndrome products	Firdapse	25	3,129	3	$ 630,106	-		-		25	3,129	3	$ 630,106
	Ruzurgi	3	360	1	$ 29,635	-		-		3	360	1	$ 29,635
Strensiq (asfotase)		89	1,236	7	$ 6,006,209	13	156	1	$1,042,784	76	1,080	6	$ 4,963,425
Varubi													
Vyondys 53													
Cryopyrin-associated periodic syndromes (CAPS) products	Arcalyst												
	Ilaris	94	105	14	$ 1,750,429	-		-		94	105	14	$ 1,750,429
	Kineret	91	2,298	19	$ 489,534	1	19	1	$ 4,460	90	2,279	18	$ 485,074
Spravato		267	1,013	25	$ 258,475	50	185	6	$ 10,479	217	828	19	$ 247,995
Dupixent – addendum		7,565	28,570	1,153	$ 21,632,398	439	1,902	71	$ 146,352	7,126	26,668	1,084	$ 21,486,046
Emflaza – addendum		292	9,674	28	$ 2,191,147	-		-		292	9,674	28	$ 2,191,147
PCSK9 inhibitors – addendum	Repatha	4,479	13,102	882	$ 864,956	1,633	5,279	338	$ 169,904	2,846	7,823	544	$ 695,052
	Praluent	953	2,570	210	$ 220,236	261	674	61	$ 48,522	692	1,896	149	$ 171,714
Vimizim		51	4,875	2	$ 652,143	6	2,400	1	$ 30,947	45	2,475	1	$ 621,196
Naglazyme		13	1,560	1	$ 607,831	-		-		13	1,560	1	$ 607,831
Mepsevii													
Addendum - Calcitonin gene-related peptide (CGRP) antagonists	Aimovig	4,687	4,944	832	$ 2,359,777	418	533	91	$ 48,832	4,269	4,411	743	$ 2,310,945
	Ajovy	776	1,230	152	$ 446,207	-		-		776	1,230	152	$ 446,207
	Emgality	2,096	2,337	428	$ 1,043,565	290	367	64	$ 40,128	1,806	1,970	365	$ 1,003,437
	Vyepti	15	29	5	$ 37,856	-		-		15	29	5	$ 37,856
	Ubrelvy	3,496	38,690	950	$ 2,576,468	485	5,880	128	$ 73,359	3,011	32,810	822	$ 2,503,108
	Nurtec ODT	1,174	10,428	335	$ 914,533	12	96	3	$ 8,852	1,162	10,332	332	$ 905,681

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State of New Jersey
Department of Human Services
Division of Medical Assistance & Health Services
New Jersey Drug Utilization Review Board

NEWSLETTER

Volume 31 No. ? **November 2021**

TO: Physicians, Nurse Practitioners, Clinics, Federally Qualified Health Centers- **For Action**
Health Maintenance Organizations – **For Information Only**

SUBJECT: **Clinical News from the New Jersey Drug Utilization Review Board (NJDURB)**

PURPOSE: To provide practitioners useful clinical information on ivermectin use that the NJDURB has determined may be helpful.

BACKGROUND: The NJDURB serves as an advisory board to the New Jersey Department of Human Services and the New Jersey Department of Health and Senior Services. The Board's responsibilities include recommending clinical standards based, in part, on the evaluation of prescription drug use by participants in the State's prescription drug programs. The Board is also responsible for disseminating information that the Board has determined would encourage appropriate drug utilization.

ACTION: The New Jersey Drug Utilization Review Board (NJDURB) recently completed a review of Stromectol® (ivermectin) drug utilization. The intent was to evaluate whether ivermectin was being prescribed as an off-label treatment for the SARS-CoV-2 infection.

The Board's review demonstrated a dramatic increase in the off-label use of ivermectin. Although the FDA approved ivermectin for the treatment of some parasitic worms, head lice and skin conditions, the Centers for Disease Control and Prevention (CDC), the FDA and other professional organizations including, but not limited to the American Medical Association (AMA) and the American Society of Health-System Pharmacists (ASHP) have expressed serious concerns regarding adverse clinical reactions to the unapproved use of this medication for the treatment of the SARS-CoV-2 infection.

The NJDURB has recommended the exclusion protocol for ivermectin use described below:

- Ivermectin shall be approved for FDA- approved indications only.
- Approval shall be for no more than six (6) 3 mg tablets in ninety (90) days.
- Higher doses shall be approved with evidence of medical necessity.

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References:
1. Stromectol® prescribing information, Merck & Co. Inc., 2009
2. CDC Treatment Guidelines: https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_449.pdf

Providers are encouraged to share safety concerns or related side effects from the off-label use of ivermectin. Below are some helpful resources which may be used to educate patients.

Why You Should Not Use Ivermectin to Treat or Prevent COVID-19
https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19

AAPS Letter to AMA Re: Ivermectin and COVID
https://www.ama-assn.org/press-center/press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19

FAQ: COVID-19 and Ivermectin Intended for Animals
https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals

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Protocol for the Safe and Efficient Use of PCSK9 Inhibitors

Approved January 2016
Updated July 2020
Updated January 2022

Addendum:

1. FDA approved use of **Praluent** as an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C. – April 2021
2. FDA approved use of **Repatha** in pediatric patients age 10 and older with heterozygous familial hypercholesterolemia (HeFH) – September 2021
3. FDA approved use of **Repatha** in pediatric patients age 10 and older with homozygous familial hypercholesterolemia (HoFH) – September 2021

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

Criteria for Approval:

Patient's diagnosis must be confirmed by the following:

1. Laboratory documentation of LDL from within the past 30 days must be received and the patient 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)

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b. LDL-C ≥ 100 mg/dL for familial hypercholesterolemia without documented ASCVD

2. Patient must not be receiving another PCSK9 inhibitor
3. For HoFH, the patient must not be receiving lomitapide (Juxtapid®) or mipomersen (Kynamro®)
4. Patient is not pregnant
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. 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
   c. 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. **Heterozygous familial hypercholesterolemia (HeFH)**
   a. Patient is 18 years of age or older for Praluent 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
      (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
      (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
      (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 (drug names, daily dosages, dates and length of therapy must be provided) **AND** has tried TWO maximally tolerated statins unless the patient has a documented contraindication or intolerance to statin therapy. Two maximally tolerated statin therapies are defined as one of the following (a or b):
   a. Two high-intensity statin therapies (i.e. rosuvastatin 20-40 mg, atorvastatin 40-80 mg) **OR**
   b. Documentation that the patient was not able to tolerate two high-intensity statins, but used a high-intensity statin and a lower daily dose of statin OR two lower intensity statins AND the prescriber provides a documented reason for not using the higher dose.
10. 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).
11. 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 inhibitor.
2. For homozygous familial hypercholesterolemia, the patient must not be concurrently receiving lomitapide (Juxtapid) or mipomersen (Kynamro).
3. The patient must not be pregnant.
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 the past 30 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

7. *Premature: < 55 years in men; < 60 years in women
8. ** 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. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.
4. Alirocumab. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: http://www.clinical pharmacology.com. Updated 8/2018
5. Evolocumab. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: http://www.clinical pharmacology.com. Updated 8/2018
6. Wong ND, Shapiro, MD. Interpreting the Findings From the Recent PCSK9 Monoclonal Antibody Cardiovascular Outcomes Trials. Front Cardiovasc Med. 2019; 6: 14. Accessed online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6414420/
7. Schwartz GG, Steg PG, Szarek M, et al. Alirocumab and cardiovascular outcomes after acute coronary syndrome. N Engl J Med 2018; 379:2097-2107.

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8. 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.
9. 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

Protocol for Spravato® (esketamine) Nasal Spray

Approved July 2020
Updated January 2022

Addendum:
Added new FDA-approved indication for "depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior" – July 2020

Background:
Spravato is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults and for depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

Criteria for approval:

1. Patient is 18 years of age or older
   A. Patient has been diagnosed with treatment-resistant depression; OR
   B. Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

2. (a) For TRD, there is documentation showing that the patient had therapeutic failure or had an intolerance for at least 3 weeks each to at least two (2) antidepressants unless the patient has contraindications to all antidepressants.
   (b) For MDD with suicidal ideation or behavior, 2-drugs trial not applicable

3. Patient must use Spravato nasal spray in conjunction with an oral antidepressant therapy

4. Spravato will be administered under the supervision of a healthcare provider and the patient will be monitored for at least 2 hours after administration

5. Patient has been assessed and determined not to be at risk for abuse and misuse of Spravato

6. Patient has no contraindications to therapy:
   a. Patient has no aneurysmal vascular disease (including in the brain, chest, abdominal aorta, arms and legs) or arteriovenous malformation, or history of bleeding in the brain
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

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Continuation of therapy:

1. Documentation showing the patient responded to therapy demonstrated by an improvement from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS)

2. Patient must use Spravato nasal spray in conjunction with an oral antidepressant therapy

3. Spravato will be administered under the supervision of a healthcare provider and the patient will be monitored for at least 2 hours after administration

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, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

Warning: Because of the risks of serious adverse outcomes resulting from sedation, dissociation, and abuse and misuse, SPRAVATO is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the SPRAVATO REMS

References:
1. Spravato [package insert]. Janssen Pharmaceuticals, Inc., Titusville, NJ 08560. July 2020
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2018. Updated periodically
3. Canuso C, Singh J, et al: Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of Symptoms of Depression and Suicidality in Patients at Imminent Risk for Suicide: Results of a Double-Blind, Randomized, Placebo-Controlled Study. Am J Psychiatry. 2018. Accessed online on May 24, 2019 at: https://adaa.org/sites/default/files/Canuso-AJP-2018.pdf

Proposed Protocol for Gamifant® (emapalumab-lzsg)

January 2022

Background:

Hemophagocytic lymphohistiocytosis (HLH) is a rapidly progressive, life-threatening syndrome of excessive immune activation.

Gamifant *is an interferon gamma (IFNγ) blocking antibody indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.*

Criteria for approval:

Patient meets **ALL** the following:

1. Patient has a diagnosis of HLH confirmed by one of the following:
   a. Has a genetic mutation known to cause HLH
   b. Has a family history consistent with primary HLH
   c. Has at least FIVE of the following 8 diagnostic criteria per HLH-2004 protocol and the American Histiocyte Society:
      i) Fever
      ii) Splenomegaly
      iii) Cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9g/dL (< 10g/dL in infants < 4 weeks), platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L)
      iv) Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL or hypofibrinogenemia ≤ 1.5g/dL)
      v) Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
      vi) Low or absent NK cell activity
      vii) Ferritin ≥ 500 mcg/L
      viii) Elevation of soluble CD25 (> 2 SD from the mean); AND

2. Patient has active disease that is refractory and has an inadequate response to, has a contraindication, or is intolerant to conventional HLH therapy (e.g., dexamethasone, etoposide, cyclosporine, anti-thymocyte globulin, etc.);

3. The prescribing physician is a Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders;

4. Patient is a candidate for hematopoietic stem cell transplant (HSCT)

5. Patient is receiving prophylactic pre-medications (for example antivirals, antibiotics, antifungals) for Herpes Zoster, Pneumocystis jirovecii, and other fungal infections

6. Patient has been screened for tuberculosis, adenovirus, Epstein-Barr Virus and Cytomegalovirus as clinically indicated

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7. Gamifant is used in combination with dexamethasone

8. Patient is tested for tuberculosis prior to initiation of therapy

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. Weight must be received for drugs that have weight-based dosing

Continuation of therapy:

1. Documentation of positive clinical response demonstrated in changes in the laboratory parameters in 1c above

2. Patient is receiving prophylactic pre-medications (for example antivirals, antibiotics, antifungals) for Herpes Zoster, Pneumocystis jirovecii, and other fungal infections;

3. Patient has been monitored while on therapy for tuberculosis, adenovirus, Epstein-Barr Virus and Cytomegalovirus; AND

4. Gamifant is used in combination with dexamethasone

5. For dose increases, the member's weight must be received

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

References:

1. Gamifant® [prescribing information]. Sobi, Inc., Watham, MA 02452; June 2020.
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. McClain KL. Treatment and prognosis of hemophagocytic lumphohistiocytosis. UpToDate. Updated May 11, 2020. Accessed November 2021.
4. Jordan MB, Allen CA, et al. How I treat hemophagocytic lymphohistiocytosis. Blood. 2011 Oct 13; 118(15): 4041–4052.
5. La Rosee P, Horne A, et al. Recommendations for the management of hemophagocytic lymphohistiocytosis in adults. Blood (2019) 133 (23): 2465–2477.

Proposed Protocol for Nitisinone Products

January 2022

Nityr (nitisinone tablets)
Orfadin (nitisinone capsules and suspension)

Background:

Tyrosinemia type 1 is a rare autosomal recessive genetic metabolic disorder characterized by lack of the enzyme fumarylacetoacetate hydrolase (FAH), which is needed for the final break down of the amino acid tyrosine. Failure to properly break down tyrosine leads to abnormal accumulation of tyrosine and its metabolites in the liver, potentially resulting in severe liver disease. Tyrosine may also accumulate in the kidneys and central nervous system.

***Nityr and Orfadin** are hydroxyphenyl-pyruvate dioxygenase inhibitors indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.*

Criteria for approval:

1. Patient has a diagnosis of Hereditary Tyrosinemia (HT-1) confirmed by one of the following:
   a. Genetic testing confirmed a mutation of the FAH gene; OR
   b. The patient has elevated serum levels of alpha-fetoprotein (AFP) and succinylacetone; OR
   c. The patient was diagnosed with HT-1 by the presence of succinylacetone in the urine or plasma

2. Medication is prescribed in conjunction with a tyrosine and phenylalanine restriction diet

3. Patient will not take Nityr and Orfadin concurrently

4. Medication is prescribed by or in consultation with a metabolic disease specialist

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

6. Weight must be monitored for drugs that have weight-based dosing

7. Patient's platelet and white blood cell counts will be monitored during therapy

Continuation of therapy:

1. Documentation that patient has disease stabilization or improvement from baseline

2. Patient is tolerating treatment

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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

References:

1. Nityr (nitisinone) [package insert]. Cycle Pharmaceutical Ltd., Cambridge, UK; November 2018.
2. Orfadin (nitisinone) [package insert]. Apoteket Produktion & Laboratorier AB, Sweden; May 2019.
3. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
4. National Organization for Rare Disorders. Tyrosinemia type I. NORD Compendium of Rare Diseases and Disorders. [New Rochelle, NY] https://rarediseases.org/rare-diseases/tyrosinemia-type-1/ Accessed November 29, 2021
5. Chinsky JM et al. Diagnosis and treatment of tyrosinemia type I: a US and Canadian consensus group review and recommendations. Genetics in Medicine volume 19, page1380 (2017)

Proposed Protocol for Lucemyra® (lofexidine)

January 2022

Background:

Medically supervised opioid withdrawal, also known as detoxification, involves the administration of medication to reduce the severity of withdrawal symptoms that occur when an opioid-dependent patient stops using opioids.

***Lucemyra** is a central alpha-2 adrenergic agonist indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.*

Criteria for approval:

Patient meets **ALL** the following:

1. Patient is ≥18 years old
2. Diagnosis of opioid use disorder
3. Patient is currently undergoing or is scheduled to undergo abrupt opioid discontinuation
4. Medication is prescribed by or in consultation with a physician specializing in pain management or addiction treatment
5. Patient has tried and has an inadequate response or intolerance, contraindication to oral clonidine or clonidine patch for opioid withdrawal
6. Patient has no history of congenital long QT syndrome; or will use Lucemyra with caution
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

References:

1. Lucemyra® [prescribing information]. US WorldMeds, LLC, 4441 Springdale Road, Louisville, KY 40241
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Sevarino KA. Medically supervised opioid withdrawal during treatment for addiction. UpToDate. Updated August 18, 2020. https://www.uptodate.com/contents/medically-supervised-opioid-withdrawal-during-treatment-for-addiction Accessed November 12, 2021

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Proposed Protocol for Paxlovid® (nirmatrelvir tablets; ritonavir tablets)

January 2022

Indication (Emergency Use Authorization only):

Paxlovid *is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (aged >12 years and weight >40 kg)* ***testing positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus, and who are at high risk for progression to severe COVID-19****, including hospitalization or death.*

Criteria for approval:

1. Patient is 12 years and older
2. **Paxlovid** will be approved for FDA-approved indications ONLY.
3. ***Approval will be for no more than 6 tablets per day and no more than 30 tablets per 90 days.***
4. Higher doses or quantities will be approved with evidence of medical necessity.

Dose:

300 mg nirmatrelvir plus 100 mg ritonavir PO BID x 5 days
Initiate as soon as possible after COVID-19 diagnosis and within 5 days of symptom onset

References:

1. Fact sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid. Pfizer Labs. Division of Pfizer Inc. New York, NY 10017. December 2021.
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. FDA Emergency Use Authorization 105. Pfizer Labs. Division of Pfizer Inc. New York, NY 10017. December 22, 2021. https://www.fda.gov/media/155049/download Accessed online on December 30, 2021
4. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. US Department of Health and Human Services/Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Vol. 70 (32). August 13, 2021. https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7032e1-H.pdf.
5. Ending Isolation and Precautions for People with COVID-19: Interim Guidance. Centers for Disease Control and Prevention (CDC). Last updated: Dec 28, 2021. https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

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Proposed Protocol for molnupiravir capsules

January 2022

Indication (Emergency Use Authorization only):

Molnupiravir *is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID19) in adults* ***with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19****, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.*

Criteria for approval:

1. Patient is 18 year and older
2. **Molnupiravir** will be approved for FDA-approved indications ONLY.
3. ***Approval will be for no more than 8 tablets per day and no more than 40 tablets per 90 days.***
4. Higher doses or quantities will be approved with evidence of medical necessity.

Dose:

800 mg PO q12hr for 5 days
Initiate as soon as possible after COVID-19 diagnosis and within 5 days of symptom onset

References:

1. Fact sheet for Healthcare Providers: Emergency Use Authorization for molnupiravar. Merck & Co. Inc. Whitehouse Station, NJ 08889. December 2021.
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. US Department of Health and Human Services/Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Vol. 70 (32). August 13, 2021. https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7032e1-H.pdf.
4. Ending Isolation and Precautions for People with COVID-19: Interim Guidance. Centers for Disease Control and Prevention (CDC). Last updated: Dec 28, 2021. https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

NJ DURB Prior Authorization Denial Report - 3rd Quarter 2021 (July - Sept)

	FFS	Aetna	Amerigroup	Horizon	UHC	Wellcare
Total # of Enrolled Beneficiaries	**62,391**	**119,857**	**240,350**	**1,085,359**	**397,918**	**103,507**
Total # of Pharmacy Claims Processed	**1,228,970**	**241,486**	**1,017,829**	**3,550,272**	**1,015,752**	**361,547**
Total # of Members Requesting Prior Authorization*	**2,676**	**2,823**	**5,576**	**15,215**	**7,072**	**1,708**
Total Prior Authorizations Requests Received**	**5,087 (0.4%)**	**4,094 (1.7%)**	**7,641 (0.8%)**	**21,667 (0.6%)**	**8,817 (0.9%)**	**2,559 (0.7%)**
Received Requests Denials	**309 (6.1%)**	**1,457 (35.6%)**	**2,736 (35.8%)**	**6,881 (31.8%)**	**3,783 (42.9%)**	**933 (36.5%)**
Without Non-formulary Denials	**309 (6.1%)**	**549 (13.4%)**	**1,344 (17.6%)**	**2,550 (11.8%)**	**1,173 (13.3%)**	**226 (8.8%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	163 (52.8%)	424 (29.1%)	1,228 (44.9%)	2,329 (33.8%)	1,001 (26.5%)	184 (19.7%)
Excluded Benefit	146 (47.2%)	58 (4.0%)	102 (3.7%)	221 (3.2%)	171 (4.6%)	2 (0.2%)
Non-formulary	0 (0.0%)	908 (62.3%)	1,392 (50.9%)	4,331 (62.9%)	2,609 (69.0%)	707 (75.8%)
Other	0 (0.0%)	67 (4.6%)	14 (0.5%)	0 (0.0%)	1 (0.0%)	40 (4.3%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	1.9%	5.5%	6.0%	3.4%	5.3%	2.5%
Antidepressants	0.0%	1.8%	0.6%	2.8%	1.1%	0.3%
Antihypertensives	0.0%	0.5%	0.3%	0.9%	3.0%	0.4%
Antianxiety	2.6%	0.1%	0.0%	0.2%	0.1%	0.0%
Antidiabetics (oral and insulin)	1.9%	8.0%	4.1%	14.5%	11.1%	14.7%
Anticoagulants	0.3%	1.7%	0.0%	0.1%	0.2%	0.6%
Thyroid agents	0.0%	0.4%	0.1%	0.2%	0.4%	0.6%
Ulcer Drugs/Antispasmodics/Anticholinergics	31.4%	2.8%	1.8%	2.6%	2.2%	1.6%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	0.0%	9.6%	2.5%	3.2%	2.6%	4.7%
Antipsychotic/Antimanic agents	5.8%	1.4%	0.4%	3.1%	1.6%	1.5%
Antiasthmatic and Bronchodilator agents	2.6%	7.9%	1.9%	7.5%	7.1%	4.3%
Antivirals (includes both HIV and Hep C)	1.9%	1.9%	0.7%	1.3%	1.1%	2.9%
Digestive Aids (Digestive Enzymes)	0.3%	0.3%	0.1%	0.1%	0.0%	0.2%
Anticonvulsants	1.0%	3.6%	0.3%	1.6%	2.7%	2.8%
Migraine Products	0.3%	2.7%	2.7%	3.8%	3.8%	3.9%
Analgesics Anti-inflammatory	1.9%	3.7%	0.6%	1.8%	2.8%	3.8%
Analgesic Opioids	2.6%	3.4%	1.1%	2.9%	2.5%	3.5%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	1.3%	1.3%	1.2%	1.0%	3.0%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	1.4%	0.8%	0.6%	0.3%	0.9%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.1%		0.0%	0.1%	0.0%
Dermatologics (Antipsoriatics-Systemic)	0.0%	13.9%	9.8%	14.3%	18.8%	15.7%

* 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

January 19, 2022

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
October 2021	Addendum for Duchenne muscular dystrophy products	- The Board recommended the protocol with suggestion to reword criterion #6	Updated version will be presented at the next meeting
	Proposed protocol for Aduhelm® (aducanumab)	- The Board recommended the protocol with suggestion to change Mini-Mental State Examination (MMSE) scores from 24-30 to 24-29	Updated version will be presented at the next meeting
	Proposed protocol for Bronchitol® (mannitol)	- The Board recommended the protocol with suggestion to reword criterion #4	Updated version will be presented at the next meeting
	Proposed protocol for Imcivree® (setmelanotide)	- The Board recommended the protocol	
	Proposed exclusion protocol for Stromectol® (ivermectin)	- The Board recommended the protocol contingent on sending out a "Dear Prescriber" letter	A "Dear Prescriber" letter will be sent out as soon as it is approved by the Board
July 2021	Addendum for direct acting antiretrovirals (DAAs) for HCV protocol	- The Board recommended approval of the protocol	
	Addendum for Dupixent® (dupilumab) protocol	- The Board recommended approval of the protocol	
	Addendum for Vyondys® (golodirsen) protocol	- The Board recommended approval of the protocol with a change in the name to "Duchenne Muscular Dystrophy protocol"	Update will be presented at the next meeting
	Addendum for Epidiolex® (cannabidiol) protocol		
	Addendum for Cablivi® (caplacizumab) protocol	- The Board recommended approval of the protocol	
	Proposed protocol for Cabenuva® (cabotegravir/rilpivirine) injectable	- The Board recommended approval of the protocol with a rewording of criterion # A-d	This criterion will be updated
	Proposed protocol for biologic response modifier products used in plaque psoriasis	- The Board recommended approval of the protocol with a change in criterion #5. They also recommended alerting the New Jersey Dermatology Society about the change	This criterion will be updated
	Proposed protocol for Lumizyme® (alglucosidase alfa)	- The Board recommended approval of the protocol	
	Proposed protocol for Myalept® (metreleptin)	- The Board recommended approval of the protocol	

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Summary of DURB Recommendations

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
April 2021	Proposed protocol for Korlym (mifepristone)	- The Board recommended the approval of the protocol	
	Proposed protocol for Juxtapid (lomitapide)	- The Board recommended the approval of the protocol	
	Proposed protocol for Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) products	- The Board recommended the approval of the protocol	
January 2021	Addendum to opioid protocol	- The Board recommended the approval of the addendum previously approved in October 2018. They recommended a change in criterion #7	This criterion will be reworded
	Protocol for Daraprim (pyrimethamine)	- The Board recommended the approval of the protocol	
	Protocol for Increlex (mecasermin)	- The Board recommended the approval of the protocol	
	Protocol for exclusion on Victoza (liraglutide)	- The Board recommended the approval of the protocol	

Protocol for Duchenne Muscular Dystrophy Products

Updated October 2021

Approved July 2020
Updated July 2021 - Added viltolarsen (Viltepso®) – FDA-approved in August 2020

Exondys 51 (eteplirsen)
Vyondys 53 (golodirsen)
Viltepso (viltolarsen)
Amondys 45 (casimersen)

Addendum:
- Added casimersen (Amondys 45) - FDA-approved in February 2021
- Changed name to "Protocol for Duchenne Muscular Dystrophy Products"

Background:
Eteplirsen (Exondys 51)® is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

Golodirsen (Vyondys 53®) is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

Viltolarsen (Viltepso®) is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

Casimersen (Amondys 45®) is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping

Limitations: This indication was approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Vyondys 53/Viltepso/Amondys 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Criteria for Approval:

1. Patient must have the diagnosis of Duchenne Muscular Dystrophy (DMD).

2. Submission of medical records including the following:

a. For Exondys 51: Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 51 skipping
b. For Vyondys 53 and Viltepso: Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 53 skipping.
c. For Amondys 45: Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 45 skipping.
d. Baseline renal function tests (i.e., glomerular filtration rate GFR) as required by medication's label

3. Patient has been stable on systemic corticosteroid regimen for at least 24 weeks, unless contraindicated or experienced significant adverse effects (must receive documentation)

4. Prescribed by or in consultation with a pediatric/adult neurologist or a physician who is an expert in the treatment of DMD, other neuromuscular disorders

5. Prescriber understands that continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials (PI)

6. Patient's kidney function will be evaluated before and during treatment as required by medication's label

7. Weight must be received for drugs that have weight-based dosing

8. 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

9. Patient will not use golodirsen (Vyondys 53®) together with viltolarsen (Viltepso®)

Continuation of therapy:

1. Updated chart notes demonstrating positive clinical response to therapy (such as improvement and/or stabilization compared to baseline)

2. Prescribed by or in consultation with a pediatric/adult neurologist or a physician who is an expert in the treatment of DMD, other neuromuscular disorders

3. For dose increases, the member's weight must be received

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, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

5. Patient will not use golodirsen (Vyondys 53®) together with viltolarsen (Viltepso®)

References:

1. Exondys 51 [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; September 2016.
2. Vyondys 53 [package insert]. Sarepta Therapeutics, Inc.; Cambridge, MA. March 2020.
3. Viltepso [package insert]. NS Pharma, Inc. Paramus, NJ 07652
4. Amondys 45 [package insert]. Sarepta Therapeutics, Inc; Cambridge MA. February 2021
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically
6. Mendell JR, et al; Eteplirsen Study Group. Eteplirsen for the treatment of Duchenne muscular dystrophy. Ann Neurol. 2013;74(5):637-647.
7. Lee JJA, Saito T et al. Direct Reprogramming of Human DMD Fibroblasts into Myotubes for In Vitro Evaluation of Antisense-Mediated Exon Skipping and Exons 45-55 Skipping Accomplished by Rescue of Dystrophin Expression. Methods Mol Biol. 2018; 1828: 141-150
8. Bushby K, Finkel R, Birnkrant DJ, Case LE, Clemens PR, Cripe L, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol; 2010 Jan; 9(1):77 93.

Protocol for Aduhelm® (aducanumab)

Approved October 2021

Background:

Alzheimer's is the most common cause of dementia, a general term for memory loss and other cognitive abilities serious enough to interfere with daily life. Alzheimer's disease accounts for 60-80% of dementia cases.

***Aduhelm** is an amyloid beta-derived antibody indicated for the treatment of Alzheimer's disease (AD).*

This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Aduhelm. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Criteria for approval:

Patient meets **ALL** of the following with documentation:

1. Diagnosis of mild cognitive impairment or mild dementia stage Alzheimer's disease
2. Patient is ≥ 50 years of age
3. Patient meets all the following testing requirements:
   a) Mini Mental State Examination (MMSE) scores between 24-29
   b) Clinical Dementia Rating (CDR) global score of 0.5
   c) Positive amyloid Positron Emission Tomography (PET) scan
   d) Recent (within one year) brain MRI prior to initiating treatment
4. Absence of significant levels of impairment in other cognitive domains
5. Medication is prescribed by or in consultation with a neurologist, geropsychiatrist, geriatrician, or a physician who specializes in the treatment of Alzheimer's disease
6. Provider attests to have an MRI completed prior to the 7th and 12th dose to evaluate for the presence of asymptomatic Amyloid Related Imaging Abnormalities (ARIA)
7. Current patient's weight should be measured
8. 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. Improvement or stabilization in ONE of the following compared to baseline at week 78:
   a. MMSE score
   b. CDR score

2. MRI is done prior to the 7th and 12th dose to evaluate for the presence of asymptomatic Amyloid Related Imaging Abnormalities (ARIA)
   a) If radiographic presence of severe ARIA-H is observed, (10 or more new incident microhemorrhages or more than 2 focal areas of superficial siderosis, a clinical evaluation and a follow-up MRI demonstrating radiographic stabilization is submitted (i.e., no increase in size or number of ARIA-H)

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

4. Current patient's weight should be measured

References:

1. Aduhelm® injection [prescribing information]. Biogen Inc. Cambridge, MA 02142
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. CDR® Dementia Staging Instrument. Knight Alzheimer Disease Research Center. 4488 Forest Park, Suite 101, St. Louis, Missouri 63108. Accessed July 1, 2021 at: https://knightadrc.wustl.edu/cdr/cdr.htm
4. Creavin ST, Wisniewski S, Noel-Storr AH et al. Mini-Mental State Examination (MMSE) for the detection of dementia in people aged over 65. Cochrane, January 2016
5. ClinicalTrials.gov. 221AD301 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (ENGAGE). Available at: https://clinicaltrials.gov/ct2/show/NCT02477800
6. ClinicalTrials.gov. 221AD302 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (EMERGE). Available at: https://clinicaltrials.gov/ct2/show/NCT02484547
7. D. Press, M. Alexander; (2021). Treatment of Alzheimer disease. In J. Wilterdink (Ed.) *UpToDate*. Retrieved July 8, 2021, from https://www.uptodate.com/contents/treatment-of-alzheimer-disease?search=Aduhelm&source=search_result&selectedTitle=2~7&usage_type=default&display_rank=1#H2549013834

Protocol for Bronchitol® (mannitol)

Approved October 2021

Background:

***Bronchitol**, is a sugar alcohol indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis.*

Criteria for approval:

Patient meets ALL the following:

1. The patient is 18 years of age or older
2. The patient has a diagnosis of cystic fibrosis (CF)
3. The patient has passed the Bronchitol Tolerance Test (documentation will be required)
4. The patient will use Bronchitol with standard CF therapies (e.g., bronchodilators, antibiotics, chest physiotherapy, etc.). A short-acting bronchodilator is used by inhalation 5-15 minutes before every dose of Bronchitol.
5. Medication is prescribed by or in consultation with a pulmonologist or a specialist in the treatment of CF
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. Medication is prescribed by or in consultation with a pulmonologist or a specialist in the treatment of CF
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. Bronchitol injection [prescribing information]. Chiesi USA, Inc. Cary, NC 27518. October 2020
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. P.A. Flume, E. Amelina, C.L. Daines et al., Efficacy and safety of inhaled dry-powder mannitol in adults with cystic fibrosis: An international, randomized controlled study, Journal of Cystic Fibrosis, https://doi.org/10.1016/j.jcf.2021.02.011 Accessed August 5, 2021