NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

January 25, 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 October 19, 2022, meeting

IV. Review of draft meeting summary for October 19, 2022, meeting (pages 3-7)

V. Secretary's report (page 8)

VI. Old Business
- A. Ivermectin utilization report (YTD 12-19- 2022) [page 9]
- B. CGRP utilization report 2021 versus 2022 (YTD 12-19-22) [page10]
- C. Semaglutide utilization report January 2021 – September 2022, as of 12-19-22 (pages 11-12)
- D. Review of impact of Inflation Reduction Act on insulin cost
- E. Summary of DURB suggested changes to proposed protocols (see links to protocols) [page 13]
  - i. Glucagon-like peptide-1 receptor agonists for T2D
  - ii. Cholbam® (cholic acid)

VII. New Business
- A. Proposed addendum to Spinraza®/Zolgensma® protocols (pages 14-16)
- B. Proposed addendum to Imcivree® protocol (pages 17-18)
- C. Proposed addendum to GLP-1 agonists protocol (pages 19-20)
- D. Proposed addendum to Dupixent® protocol (atopic dermatitis) [pages 21-22]
- E. Proposed protocol for Gattex® (teduglutide) [pages 23-24]
- F. Proposed protocol for Hyftor® (sirolimus) [page 25]

VIII. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ HMO 3rd Quarter 2022 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. **Wisconsin Supreme Court to hear ivermectin treatment case**
   https://www.beckershospitalreview.com/hospital-physician-relationships/wisconsin-supreme-court-to-hear-ivermectin-treatment-case.html

1

2. **FDA Announces Preliminary Assessment that Certain Naloxone Products Have the Potential to be Safe and Effective for Over-the-Counter Use**
   FDA Announces Preliminary Assessment that Certain Naloxone Products Have the Potential to be Safe and Effective for Over-the-Counter Use | FDA

3. **The TikTok trend that triggered a diabetes drug shortage**
   https://www.mdedge.com/endocrinology/article/259863/obesity/tiktok-trend-triggered-diabetes-drug-shortage

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

IX. Updated Materials:
   a. Proposed protocol for Glucagon-like peptide-1 receptor agonists used for T2D – approved October 2022
   b. Proposed protocol for Cholbam® (cholic acid) – approved October 2022

October 19, 2022 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 13, 2022, 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 Cw		- The Department is working with the Commissioners to review and sign off on DURB-recommended protocols for: January 2022, April 2022, and July 2022. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members. - The proposed dates for **2023** DURB meetings are as follows: - Wednesday, January 25 - Wednesday, April 19 - Wednesday, July 19 - Wednesday, October 18. If the Board approves these dates, it will be published for the general public. - Dr. Swee wanted to know when the Board will know if these meetings will be in person or remote. Dr. Emenike responded that nothing has changed but the State will let us know prior to the January meeting. - The Board approved the proposed dates.

October 19, 2022 DURB Meeting Summary (draft)

Issue	Action	Notes
		- The DURB SFY 2021 annual report was signed off by the DHS and DOH Commissioners. - Dr. Marcus wanted to know what the Governor "ending the HIV Epidemic Initiative" means. Mr. Vaccaro, R.Ph., explained that all prior authorization for this class of drugs has been removed; patients will be allowed to receive up to 90-day supply if they request it within 30 days of dis-enrolling from Managed Care.
Old Business		
Ivermectin utilization report (January - July 2022)		The Board reviewed a follow-up report for ivermectin utilization for the period of January 2022 to July 2022. They concluded that there was little use of the product for COVID-19 which was a prior concern and reason for the report.
MCO Collaborative Response		The Board reviewed a collaborative report from the MCOs in response to questions related to the quarterly PA denial reports. Dr. Swee expressed concern about the disparity among the MCO plans. Dr. Lind cautioned against making conclusions about the PA rates because of the different processes and approach by individual plans. The Board requested similar report quarterly. Dr. Swee said that he was surprised by the churn rate of 0.33 percent, which he said, was low compared to the impression we were previously given.
Proposed Protocol addendum to Calcitonin Gene-Related Peptide (CGRP) antagonists for migraines	Approved	The Board reviewed a proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) used in the treatment of migraines. Dr. Swee said that the updated protocol with the accompanying algorithm was much better. He also informed the Board that neurologists say the products are effective and are leaning towards using them more. So, the Board will keep a close eye on the utilization. To accomplish this, he requested another utilization report in three to six months. The Board approved the addendum.
Paid Claims for semaglutide in SFY 2022 (July 2021-June 2022)		In a previous meeting, Dr. Marcus expressed concern about the use of semaglutide formulations (Ozempic and Rybelsus) for weight loss even though they were not approved for that indication. Although there was a 30% increase in utilization from July 2021 thru June 2022, there was no way to confirm this was due to inappropriate use. The Board requested a follow-up report for the next meeting.

October 19, 2022 DURB Meeting Summary (draft)

Issue	Action	Notes
New Business		
(A) Proposed protocol for Glucagon-Like Peptide-1 receptor agonists for T2D	Approved	The Board reviewed a proposed protocol for glucagon-like peptide-1 receptor (GLP-1) agonists used in the treatment of type 2 diabetes (T2D). The Board recommended that criterion #3 should be reworded to read: "Patient has/had suboptimal response to metformin therapy (for at least 3 months) or cannot use metformin for one of the following reasons:" Dr. Niki Patel, medical representative with Novo Nordisk informed the Board that the 2022 American Diabetic Association (ADA) guidelines recommends initiating treatment with GLP-1 agonists or sodium-glucose cotransporter 2 (SGLT2) inhibitors for patients with cardiovascular disease, atherosclerotic, or heart failure regardless of their baseline A1C, or metformin regimen. Dr. Emenike responded that although these products and SGLT2s are recommended for cardiovascular patients, they would not primarily be the first choice for the purpose of this protocol – general guideline for T2D. Dr. Swee recommended removal of criterion #1 under "continuation of therapy" which required the "documentation of positive response to therapy (HbA1C has improved from baseline). The Board recommended the protocol pending suggested changes.
(B) Proposed protocol for Biologics Used in Moderate to Severe Asthma	Approved	The Board reviewed a proposed protocol for biologics used in the treatment of moderate to severe asthma. The Board recommended the protocol.
(C) Proposed protocol for Cholbam® (cholic acid)	Approved	The Board reviewed a proposed protocol for Cholbam, a medication indicated for bile acid synthesis disorders (BASDs). Dr. Swee raised concern again about the monitoring requirement in the "continuation of therapy" section of the protocol. He stated that providers do not give drugs that are not working. Dr. Emenike explained to the Board that unlike providers on the Board and others in NJ, our experience at MEP with some prescribers in the Medicaid network demonstrated otherwise. They continued to renew medications (pain medications, benzodiazepines, hypnotics, etc.), when it was obvious that the patients no longer needed them. Dr. Marcus stated that the problem is that patients are requesting these medications from

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td></td><td></td><td>their providers because of direct-to-consumer advertising. Ms. Olson stated that without good data, there is nothing the Board can do.
The Board recommended the protocol pending the update in the continuation of therapy section.</td></tr>
<tr><td>(D) Proposed protocol for Crysvita® (burosumab-twza)</td><td>Approved</td><td>The Board reviewed a proposed protocol for Crysvita, a product indicated for the treatment of X-linked hypophosphatemia (XLH) and FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors. Dr. Swee wanted to know if we had a patient in NJ with the disease and also if the State will pay for treating a patient in another state like Pennsylvania or New York. Dr. Lind responded that all decisions are made on the basis of medical necessity not on the location of service. Ms. Desai informed the Board that there were seven patients (paid claims) for Crysvita during the last fiscal year. All were physician-administered.
The Board recommended the protocol.</td></tr>
<tr><td>Informational Highlights/Reports</td><td></td><td></td></tr>
<tr><td>1. Fee-for-Service/MCO Prior Authorization Report</td><td>Continue to monitor.</td><td>Dr. Swee commented on the continued differences in utilization denials between the plans.
Dr. Marcus made comments about variation in the HIV medications which he thinks may be related to DTC advertising.
Dr. Swee wondered when NJ will see the impact of the Inflation Reduction Act (IRA), on insulin costs. Dr. Lind responded that he has not heard any word on that but will bring information back to the Board when available. Dr. Swee requested that the subject be placed on the agenda for next meeting - possible impact on insulin utilization cost. Ms. Olson stated that the Act would not take effect until 2023.
The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 2nd 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>0.8</td><td>41</td><td>11</td></tr>
<tr><td>Amerigroup</td><td>0.9</td><td>38</td><td>13</td></tr>
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</td></tr>
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October 19, 2022 DURB Meeting Summary (draft)

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>
<table>
<tr><td>Horizon</td><td>0.7</td><td>34</td><td>12</td></tr>
<tr><td>UHC</td><td>0.9</td><td>45</td><td>16</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>33</td><td>10</td></tr>
</table>

The Board reviewed a summary of their actions from previous meetings (October 2021 thru July 2022).
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 2022 (FFS) and July 2022 (MCOs) was provided for review.

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>August 2022</td><td>$10,078,120</td><td>$10,444,703</td></tr>
<tr><td>MCOs</td><td>July 2022</td><td>$105,850,383</td><td>$147,662,453</td></tr>
</table></td></tr>
<tr><td>4. Medication Information</td><td></td><td>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 Vaccines information
b. Information for Clinicians on Investigational Therapeutics for Patients with COVID-19
c. New Jersey COVID-19 Information Hub (continuously updated)
d. New Jersey COVID-19 Dashboard
e. Know Your Treatment Options for COVID-19 - FDA</td></tr>
<tr><td>Follow up items:

2</td><td></td><td>A. Ivermectin utilization report - update
B. MCO response to the Board's PA denials report questions - update
B. CGRP antagonists for migraine utilization quarterly report
C. Semaglutide utilization report – update
D. Review of the effect of the Inflation Reduction Act on insulin utilization (agenda item)</td></tr>
</table>

NEW JERSEY DRUG UTILIZATION REVIEW BOARD

January 25, 2023

Secretary's Report:

1. The Commissioners have approved DURB-recommended protocols for January 2022.

2. The department is working with the Commissioners to review and sign off on DURB-recommended protocols for:
   - April 2022
   - July 2022
   - October 2022

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

4. Our MCO partners have informed us that they will work with the Board on another collaborative response to the PA denials report but will need more time because this will be done manually and therefore labor-intensive.

5. Insulin cost sharing (reduction) as referenced in the Inflation Reduction Act of 2022 is scheduled to take effect on January 1, 2023. The Act will have no impact on NJ Medicaid population.

Ivermectin Utilization Report:
January – November 2022

As many pharmacy claims do not have a diagnosis attached to them, medical claims within 30 days prior by the same provider were reviewed to identify the ivermectin indication. Use of ivermectin was categorized into the following categories:

- Evidence based indications [FDA labeled or off-label indications (compendia approved)]ex: onchocerciasis, strongyloidiasis; scabies, lice
- Suspected Covid-19 ex: viral infection, novel coronavirus
- Unknown diagnosis – medical claims diagnosis was unrelated to any ivermectin indications

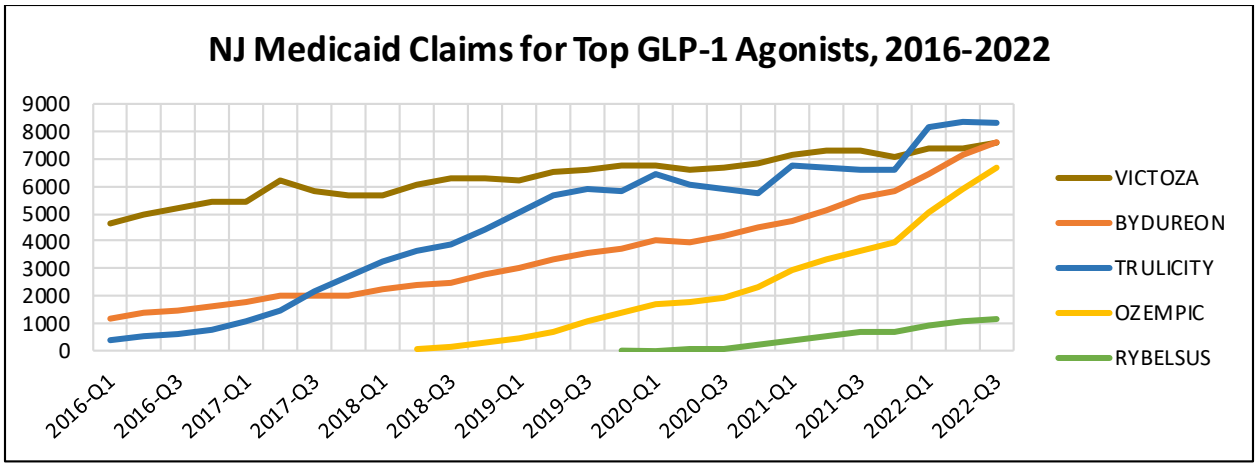
	JAN-JUN 2022	JUL-NOV 2022
SUSPECTED COVID-19	29	6
UNKNOWN DIAGNOSIS	156	152
EVIDENCE BASED INDICATION	88	74
TOTAL	**273**	**232**

367 ivermectin pharmacy claims were identified during this period (January to November 2022) and 505 associated medical claims were reviewed. None of the pharmacy claims were for higher ivermectin doses, despite some of the indications being suspected Covid-19.

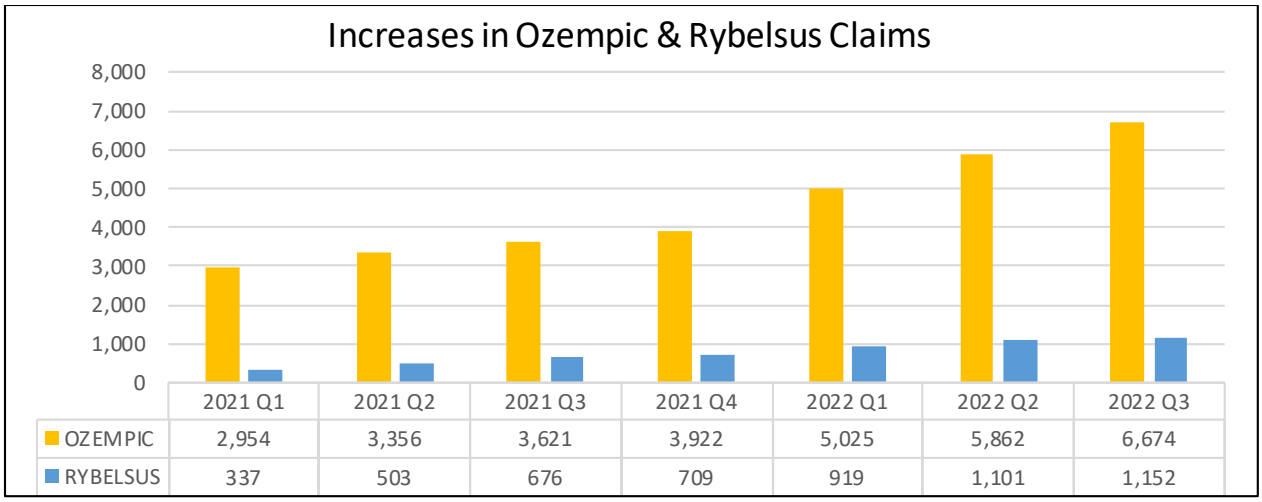
CGRP Antagonist Utilization Information:

INDICATION	CLAIMS 2021	CLAIMS 2022	PERCENT INCREASE
MIGRAINE PREVENTION	8242	10429	27%
BOTH PREVENTION AND ACUTE TREATMENT	1,318	3,044	131%
ACUTE MIGRAINE TREATMENT	3,855	5,638	46%
TOTAL	***13415***	***19111***	***42%***

Semaglutide Utilization Report



In response to the DURB's concerns regarding the use of semaglutide for weight loss, utilization trends of semaglutide products, as well as other agents in the same class, were reviewed. While steady increases in utilization of both Rybelsus and Ozempic were seen, there was also increased utilization of other products in the class, including those that are not indicated for weight management. The State found no supportive evidence to demonstrate the use of GLP-1 Receptor Agonists for weight management. In order to ensure that all utilization is for diabetes mangement the State has in place prior authorization requirements and quanitity limits on GLP-1 receptor agonists.



Drug	Q1 2022	Q1-Q2 Percent Change	Q2 2022	Q2-Q3 Percent Change	Q3 2022
Ozempic	5,025	+ 17%	5,862	+ 14%	6,674
Rybelsus	919	+ 20%	1,101	+ 5%	1,152

Summary of Board-Suggested Changes to Proposed Protocols

October 2022

A. Glucagon-like peptide-1 receptor agonists for T2D: The Board recommended that criterion #3 should be reworded to read: "patient has/had suboptimal response to metformin therapy (for at least 3 months) or cannot use metformin for one of the following reasons".

B. Cholbam® (cholic acid): The Board recommended that criterion #1 in continuation of therapy requiring lab values from prescriber should be removed.

Proposed Protocol for Spinal Muscular Atrophy (SMA) Products

Updated January 2023

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

Addendum:

1. *Addition of Evrysdi® (FDA-approved August 2020) to the existing protocols for Spinraza and Zolgensma.*
2. *Creating a "Spinal Muscular Atrophy" products protocol to accommodate these medications and future products.*

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

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

Criteria for Approval:

1. Patient has a diagnosis of spinal muscular atrophy (SMA)

2. Patient has SMA types I, II, or III

3. Diagnosis is confirmed by one of the following:
   a. Molecular genetic testing showing homozygous deletions of exon 7 of SMN1; **OR**
   b. Compound heterozygous mutation of SMN1 gene

4. Prescribed by or in consultation with a pediatric/adult neurologist or a physician who is an expert in the treatment of SMA

5. Patients weight will be monitored

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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.

For Evrysdi:

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

For Spinraza:

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

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

For Zolgensma:

1. Patient is less than 2 years of age

2. Patient has bi-allelic mutations in the survival motor neuron (SMN1) gene

3. Patient does not have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence)

4. Baseline anti-AAV9 antibody testing is done, and titers is $\leq$ 1:50

5. Patient will not receive concomitant surviving motor neuron (SMN) modifying therapy (e.g., Spinraza or Evrysdi)

6. Patient will receive systemic corticosteroid equivalent to oral prednisolone 1mg/kg/day at least 1 day prior to Zolgensma infusion and will continue to receive corticosteroid therapy for at least a total of 30 days (*patient's weight information must be received/documented prior to treatment)*

7. Prescriber attests that patient has not received Zolgensma in their lifetime
8. One dose only will be approved for the treatment of SMA
9. Patient's liver function is assessed prior to administration of Zolgensma and for at least 3 months after infusion

References:

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

Proposed Addendum to Protocol for Imcivree® (setmelanotide)

January 2023

Approved October 2021

Addendum:
Addition of new FDA-approved indication for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to Bardet-Biedl syndrome (BBS) – June 16, 2022

Background:

- *Obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1) or leptin receptor (LEPR) deficiency is an ultra-rare disease caused by variants in POMC, PCSK1 or LEPR genes that impair the melanocortin-4 receptor (MC4R) pathway, which is a pathway in the hypothalamus that is responsible for regulating hunger, energy expenditure and consequently body weight. People living with obesity due to POMC, PCSK1 or LEPR deficiency struggle with extreme, insatiable hunger beginning at a young age, resulting in early-onset, severe obesity.*
- *Bardet-Biedl syndrome is a rare genetic disorder with highly variable symptoms which may include retinal degeneration, obesity, reduced kidney function, polydactyly (extra digits of the hands or feet) among many other features.*

***Imcivree** is MC4 receptor agonist indicated for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to:*

- *POMC, PCSK1, or LEPR deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).*
- *Bardet-Biedl syndrome (BBS)*

As an MC4R agonist, Imcivree is designed to restore impaired MC4R pathway activity arising due to genetic deficits upstream of the MC4 receptor.

Criteria for approval:

Patient meets **ALL** the following:

1. Diagnosis of obesity defined as:
   a. Adults (18 years or older): BMI ≥ 30 kg/m2
   b. Children (younger than 18 years old): ≥ 95th weight percentile based on growth charts

2. Diagnosis of obesity due to one of the following:
   a. POMC, PCSK1, or LEPR deficiency with genetic testing confirming that variants in the POMC, PCSK1, and/or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance
   b. Bardet-Biedl syndrome (BBS) confirmed by identification of characteristic findings (e.g., rod-cone dystrophy, polydactyly)

3. Patient is 6 years of age or older

4. Medication is prescribed by or in consultation with an endocrinologist or expert in rare genetic disorders of obesity

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5. Documentation of estimated glomerular filtration rate [eGFR] ≥ 15 mL/min/1.73 m2

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

Exclusions:

Imcivree is not indicated for the treatment of patients with the following conditions as it would not be expected to be effective:

a. Obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign
b. Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity

Continuation of therapy:

1. For members with obesity due to POMC, PCSK1, or LEPR deficiency: Member is responding positively to therapy as evidenced by one of the following:
   a. After 16 weeks of treatment: reduction in weight compared with baseline (at least 5% body weight or 5% of BMI)
   b. After 1 year: ≥ 10% reduction in weight compared with baseline
   c. After > 1 year: maintenance of ≥ 10% reduction in weight compared with baseline

2. For members with Obesity and BBS, member responded positively to 1 year of therapy with:
   a. For children younger than 18 years old: ≥ 5% reduction of baseline BMI
   b. For 18 years and older: ≥ 5% reduction of baseline body weight

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. Imcivree® injection [prescribing information]. Rhythm Pharmaceuticals, Inc. Boston, MA 021116. June 2022
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Ayers KL, Glicksberg BS et al. Melanocortin 4 Receptor Pathway Dysfunction in Obesity: Patient Stratification Aimed at MC4R Agonist Treatment. J Clin Endocrinol Metab. 2018 Jul; 103(7): 2601–2612.
4. Wabitsch M, Flück CE, et all. Natural History of Obesity Due to POMC, PCSK1, and LEPR Deficiency and the Impact of Setmelanotide. J Endocr Soc. 2022 Apr 15;6(6)
5. Forsythe, E., Beales, P. Bardet–Biedl syndrome. Eur J Hum Genet 21, 8–13 (2013)

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Proposed Addendum to the Protocol for Glucagon-Like Peptide-1 Receptor Agonists for Type 2 Diabetes

January 2023

Approved October 2022

Addendum: Exclude patients with established atherosclerotic cardiovascular disease (ASCVD) from trial of metformin prior to treatment with GLP-1 receptor agonists

Adlyxin (lixisenatide)
Bydureon, Bydureon Bcise (exenatide Microspheres)
Byetta (exenatide)
Mounjaro (tirzepatide)
Ozempic (semaglutide)
Rybelsus (semaglutide)
Soliqua (insulin glargine/lixisenatide)
Trulicity (dulaglutide)
Victoza (liraglutide) – 10 years of age and older
Xultophy (insulin degludec/liraglutide)

Background:
The GLP-1RAs have been shown to significantly improve glycemic parameters and reduce body weight. These agents work by activating GLP-1 receptors in the pancreas, which leads to enhanced insulin release and reduced glucagon release-responses that are both glucose-dependent-with a consequent low risk for hypoglycemia.

Criteria for approval:

1. Diagnosis of type 2 diabetes mellitus; **AND**

2. Patient meets the age limit for requested product when appropriate; **AND**

3. Has atherosclerotic cardiovascular disease (ASCVD) or heart failure, irrespective of metformin use; **OR**

4. Patient has/had suboptimal response to metformin therapy (for at least 3 months) or cannot use metformin for one of the following reasons:
    a. Has a diagnosis of Crohn's disease, irritable bowel syndrome, or Ulcerative Colitis
    b. Has severe renal impairment (eGFR below 45ml/min/1.73m^2)
    c. Intolerance to metformin therapy
    d. Contraindication to metformin therapy

5. Will not be used concurrently with other GLP-1 (glucagon-like peptide-1) agonists

6. Documentation of HbA1C $\geq$ 7 measured within the past 6 months; **AND**

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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. Patient has no contraindication for treatment

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

NOTE: There is a BOXED WARNING RISK OF THYROID C-CELL TUMORS. GLP-1 analogues are associated with thyroid cancer in patients with diabetes.

References:

1. Adlyxin [package insert]. Sanofi-Aventis U.S. LLC; Bridgewater, NJ: July 2021.
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Proposed Addendum to the Protocol for dupilumab (Dupixent®) for Atopic Dermatitis

Updated January 2023

Approved April 2019
Updated July 2020
Updated July 2021

Addendum:
Removing the requirement for trial/failure of immunosuppressant therapy for pediatric and adult patients.

Background:
Dupilumab (Dupixent®) is an interleukin-4 receptor alpha antagonist that is indicated for the treatment of moderate-to severe atopic dermatitis in pediatric and adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.

Criteria for approval:

1. Patient has a diagnosis of atopic dermatitis; **AND**

2. Patient has moderate to severe disease; **AND**

3. Patient is 6 years of age or older; **AND** *(changed December 2020)*

4. Patient has a minimum of 10% body surface area involvement OR has clinically difficult to treat areas (e.g., face, neck, genital) that interfere with quality of life; **AND**

5. Prescribed by or in consultation with a dermatologist or allergist; **AND**

6. Patient has tried and failed or has contraindication for the use of ALL of the following:
    a. One medium to very high potency topical prescription corticosteroid (see Table 1); **AND**
    b. One topical calcineurin inhibitor (e.g., Elidel®, Protopic®)

7. Patient will continue to use topical emollients concomitantly in problem areas (e.g., face, neck, genital) to help prevent flares

8. Success of treatment will be assessed regularly .

9. Patient will not be using Dupixent in combination with another biologic agent for the requested indication (e.g., Rinvoq®, Cibinqo®, Adbry®, etc. or Opzelura® cream)

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

Continuation of therapy:

1. Patient has responded to treatment as demonstrated by an improvement and/or stabilization (e.g., results) compared to baseline.

2. Patient will continue to use topical emollients concomitantly in problem areas (e.g., face, neck, genital) to help prevent flares

3. Patient will not be using Dupixent in combination with another biologic agent for the requested indication (e.g., Rinvoq®, Cibinqo®, Adbry®, etc. or Opzelura® cream)

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. For dose increase for children younger than 18 years of age, weight will be monitored (added December 2020).

References:
1. Dupixent® [package insert]. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. October 2022
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
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Proposed Protocol for Gattex® (teduglutide)

January 2023

Background: *Short bowel syndrome (SBS) is a condition that results from surgical resection or congenital disease of the small intestine which is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balances when on a conventionally accepted, normal diet.*

Gattex *is as a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of adult patients with SBS who are dependent on parenteral support.*

Criteria for approval:

1. Patient has a documented diagnosis of SBS defined as < 200 cm of viable small bowel

2. Patient is 1 year of age or older and is dependent on parenteral nutrition support

3. Patient is (an adult) dependent on parenteral nutrition/intravenous (PN/I.V.) support
   a. For at least 12 months; **AND**
   b. Requires at least 3 times per week of parenteral nutrition support; **OR**

4. The following baseline tests have been completed before initiation of treatment:
   a. Whitin 6 months prior to initiating therapy, perform bilirubin, alkaline phosphatase, lipase, and amylase tests
   b. For adult patients: within 6 months prior to initiating therapy, perform a colonoscopy with removal of polyps if applicable
   c. For pediatric patients: within 6 months prior to initiating therapy, perform fecal occult blood test; if there is unexplained blood in the stool, perform colonoscopy/sigmoidoscopy

5. Medication is prescribed by or in consultation with a gastroenterologist or a provider specializing in the patient's diagnosis

6. Weight will be monitored

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. Patient is responding to therapy, defined as:
   a. Achieving at least 20% reduction in weekly PN/I.V. from baseline; **OR**
   b. Decrease in weekly PN/I.V. volume

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

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References:

1. Gattex [prescribing information]. Takeda Pharmaceuticals America, Inc. Lexington, MA 02421. October 2022
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Cagir, B. (2021, February 16). Short-Bowel Syndrome. Medscape. Accessed November 18, 2022 at: https://emedicine.medscape.com/article/193391-overview
4. Guillen G and Atherton NS. ; Nichole S. Atherton. Short Bowel Syndrome. Stat Pearls, July 26, 2022. Accessed November 21, 2022 at: https://www.ncbi.nlm.nih.gov/books/NBK536935/

Proposed Protocol for Hyftor® (sirolimus) topical gel

January 2023

Background: *Facial angiofibroma is the most predominant cutaneous manifestation of tuberous sclerosis complex (TSC), a rare autosomal dominant genetic disorder impacting the mechanistic target of rapamycin (mTOR). Facial angiofibroma can bleed spontaneously, impair eyesight, and cause aesthetic disfiguration causing psychological and social stress.*

Hyftor *is an mTOR inhibitor immunosuppressant indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older.*

Criteria for approval:

1. Patient has a diagnosis of facial angiofibroma associated with tuberous sclerosis; **AND**
2. Patient is 6 years of age or older; **AND**
3. Patient has 3 or more papules of facial angiofibroma that are at least 2 mm in diameter with redness in each
4. Medication is prescribed by or in consultation with a dermatologist or a physician who specializes in the treatment of patients with tuberous sclerosis complex
5. Patient has completed all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiation of therapy
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. There is significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to reduction in size or color of angiofibromas).
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. Hyftor [prescribing information]. Nobelpharma America, LLC, Bethesda, MD 20814. March 2022
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Lin, Y. et al. Efficacy and Safety of Topical Mechanistic Target of Rapamycin Inhibitors for Facial Angiofibromas in Patients with Tuberous Sclerosis Complex: A Systematic Review and Network Meta-Analysis. Biomedicines 2022, 10, 826. https://doi.org/10.3390/biomedicines10040826
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NJ DURB Prior Authorization Denial Report - 3rd Quarter 2022 (July - September)

	FFS	Aetna	Amerigroup	Horizon	UHC	Wellcare
Total # of Enrolled Beneficiaries	**61,135**	**133,886**	**249,083**	**1,171,339**	**418,829**	**108,518**
Total # of Pharmacy Claims Processed	**411,127**	**511,026**	**1,026,001**	**3,664,999**	**1,022,046**	**414,800**
Total # of Members Requesting Prior Authorization*	**1,127**	**3,136**	**6,470**	**17,871**	**6,090**	**2,114**
Total Prior Authorizations Requests Received**	**2,627 (1%)**	**4,379 (1%)**	**9,025 (1%)**	**26,093 (1%)**	**7,756 (1%)**	**3,162 (1%)**
Received Requests Denials	**170 (6%)**	**1,705 (39%)**	**3,461 (38%)**	**8,761 (34%)**	**3,487 (45%)**	**991 (31%)**
Without Non-formulary Denials	**170 (6%)**	**400 (9%)**	**1,294 (14%)**	**3,201 (12%)**	**1,372 (18%)**	**283 (9%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	89 (52%)	380 (22%)	1,075 (31%)	2,928 (33%)	1,157 (33%)	281 (28%)
Excluded Benefit	81 (48%)	17 (1%)	187 (5%)	273 (3%)	215 (6%)	2 (0%)
Non-formulary	0 (0%)	1,305 (77%)	2,167 (63%)	5,560 (63%)	2,115 (61%)	708 (71%)
Other	0 (0%)	3 (0%)	32 (1%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	2.9%	6.7%	2.7%	2.4%	4.3%	4.5%
Antidepressants		1.0%	1.3%	2.4%	1.3%	0.1%
Antihypertensives		1.0%	0.5%	0.5%	0.9%	0.5%
Antianxiety		0.3%	0.0%	0.3%	0.1%	0.1%
Antidiabetics (oral and insulin)	2.9%	8.6%	3.4%	17.1%	15.2%	19.8%
Anticoagulants		0.1%	0.0%	0.1%	0.4%	0.8%
Thyroid agents		0.4%	0.2%	0.3%	0.3%	0.2%
Ulcer Drugs/Antispasmodics/Anticholinergics	30.0%	2.1%	10.1%	1.8%	2.2%	1.1%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants		8.5%	2.4%	2.7%	3.0%	6.0%
Antipsychotic/Antimanic agents	7.1%	1.3%	0.5%	3.2%	2.0%	1.6%
Antiasthmatic and Bronchodilator agents	1.8%	7.3%	1.5%	7.3%	8.5%	2.7%
Antivirals (includes both HIV and Hep C)		0.5%	0.1%	0.7%	0.7%	1.6%
Digestive Aids (Digestive Enzymes)		0.2%	0.1%	0.1%	0.1%	0.6%
Anticonvulsants	0.6%	3.7%	0.6%	1.9%	3.2%	2.5%
Migraine Products		2.2%	2.7%	3.9%	4.4%	2.4%
Analgesics Anti-inflammatory	6.5%	3.3%	1.5%	1.9%	2.0%	2.6%
Analgesic Opioids	1.2%	5.3%	1.2%	2.0%	2.6%	4.4%
Endocrine and Metabolic Agents-Misc (Growth Hormone)		1.3%	0.8%	1.2%	1.7%	1.9%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)		1.2%	0.5%	1.0%	0.4%	0.8%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)		0.1%	0.1%	0.1%	0.1%	0.2%
Dermatologics (Antipsoriatics-Systemic)		15.8%	10.5%	18.0%	16.1%	11.3%

* 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

January 25, 2023

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
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 will be 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 will be presented at the next meeting
	Proposed protocol for Crysvita (burosumab-twza)	- The Board recommended the protocol	
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 will be 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 will be 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 will be presented at the next meeting
April 2022	Proposed protocol for Hetlioz® (tasimelteon)	- The Board wanted more information about why young teens couldn't use pills and why teens and adults couldn't use the liquid	This information will be presented at the next meeting
	Proposed protocol for cysteamine products (Cystagon® and Procysbi®)	- The Board recommended the protocol	
	Proposed protocol for Revcovi® (elapegademase)	- The Board recommended the protocol	
	Proposed protocol for Luxturna® (voretigene neparvovec-rzyl)	- The Board recommended the protocol	

Summary of DURB Recommendations

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
January 2022	Addendum for proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor products protocol	- The Board recommended the addendum to the protocol	
	Addendum for Spravato® (esketamine) protocol	- The Board recommended the addendum to the protocol	
	Proposed protocol for Gamifant® (emapalumab-lzsg)	- The Board recommended the protocol with a suggestion to change criterion #1 to emphasize "primary" HLH	An updated version was presented and approved at the following meeting.
	Proposed protocol for nitisinone products	- The Board recommended the protocol with suggestions to reword criteria #4 and #6	An updated version was presented and approved at the following meeting.
	Proposed protocol for Lucemyra® (lofexidine)	- The Board recommended the protocol with suggestions to criterion #4 and delete criterion #5	An updated version was presented and approved at the following meeting.
	Proposed protocol for Paxlovid® (nirmatrelvir/ritonavir)	- The Board approved the protocol	
	Proposed protocol for molnupiravir	- The Board approved the protocol	