NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

January 20, 2021

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

AGENDA

I. Call to order in accordance with New Jersey Open Public Meeting Act
https://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/1-2021/Dr_Swee's_first_meeting_of_the_year_announcement~Jan-2021.pdf

II. Roll Call

III. Review of meeting transcript for October 28, 2020 meeting
https://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/1-2021/Transcript_October_28_2020~DURB~pds.pdf

IV. Review of draft meeting summary for October 28, 2020 meeting [pages 3-7]

V. Secretary's report [page 8]

VI. Old Business
A. United Healthcare clinical criteria not met denials report [page 9]
B. Addendum to opioid protocol [pages 10-12]

VII. New Business
A. Proposed protocol for Daraprim® (pyrimethamine) [page 13-14]
B. Proposed protocol for Increlex® (mecasermin) [page 15]
C. Proposed protocol for exclusion on Victoza® (liraglutide) [page 16]

VIII. A. Informational Highlights/Reports
1. DXC Technology/NJ HMO 3rd Quarter 2020 Prior Authorization Report [pages 17-18]
2. Summary of DURB Action Items [pages 19-20]
3. (a) DHS, DHSS and MCO Programs Top Drugs Report/Physician-administered by amount paid
https://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/1-2021/FFS_Top_Drugs_Report_(November_2020).xlsx
(b) Antiviral Drugs
https://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/1-2021/FFS_Antiviral_Drugs_(November_2020).pdf

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

3. New Jersey COVID-19 Information Hub
   https://covid19.nj.gov/

IX. Referenced Materials:

1. Opioid protocol (approved October 2018) [pages 21-22]
2. Update to Vimizim approved protocol – change of criterion #3 [pages 23-24]
3. Update to Naglazyme approved protocol – change of criterion #3 [pages 25-26]
4. Update to Mepsevii approved protocol – change of criterion #3 [pages 27-28]

October 28, 2020 DURB Meeting Summary (Draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Ms. Olson, Dr. Barberio, Dr. Gooen, Dr. Moynihan, Dr. Lind (ex-officio) Unable to attend: Mr. Schafer
Review of Minutes	Approved	Minutes from July 15, 2020 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		- All DURB-recommended protocols from July 2019 through January 2020 were signed off by the Commissioners. These include: a. Hereditary angioedema (HAE) products b. Urea cycle disorder products c. Chelating agents used in the treatment of Wilson's disease, Cystinuria, and severe, active rheumatoid arthritis d. Zolgensma® (onasemnogene abeparvovec-xioi) For October 2019: a. Hereditary transthyretin-mediated amyloidosis (ATTR) products b. Elaprase® (idursulfase) c. Gaucher disease products d. Cablivi® (caplacizumab-yhdp) For January 2020: a. Fabry disease products b. Lambert-Eaton Myasthenic Syndrome products c. Strensiq®(asfotase) - The Commissioners also signed off on the DURB Annual Report for SFY 2019. This will be forwarded for posting in the NJ Register. - Board members have received the preliminary copy of the DURB Annual Report for SFY 2020. They were instructed to review and send comments to the Secretary on or before November 30, 2020.

October 28, 2020 DURB Meeting Summary (Draft)

Issue	Action	Notes
		- Proposed DURB meeting dates for 2021 was listed in the meeting packet for board members to review and comment. The dates are listed below: Wednesday, January 20 Wednesday, April 21 Wednesday, July 14 Wednesday, October 20 - There were no updates for board members appointment and re-appointments. Dr. Swee wanted to know the status of a NJ proposed legislative action that was going to reaffirm the Board's existence with the additional requirements to report conflicts of interest on a quarterly basis. Dr. Lind responded that there has been no further updates on this issue.
Old Business		
A. United Healthcare Clinical Criteria Not Met (CCNM) report B. Review of buprenorphine utilization for pain		Dr. Mimo Odebiyi with United Healthcare (UHC) informed the Board that the Plan's prior authorization team is still working on getting some examples of denials in this category Dr. Swee requested that UHC should work on getting the report to the Board in 30 days. Dr. Odebiyi agreed to do so. The Board reviewed a report on buprenorphine utilization for the 2018 and 2019 calendar year. The purpose of the report was to see how much buprenorphine was being used for pain. The report showed that in 2018, 156 patients (7.2% of patients) received buprenorphine for pain for 146 days. In 2019, there were 250 patients (9%) for 130 days. Three hundred and twenty (15%) of patients used this product for substance abuse disorder in 2018 for 167 days while 548 (19%) used it for 156 days for the same diagnosis. Board members expressed concern about the number of patients without medical claims who received this product (1,595 and 1,959) in 2018 and 2019 respectively. Mr. Ed Vaccaro, R.Ph., explained that due to lack of access to network providers, some of the patients pay cash for their medication

Issue	Action	Notes
C. Addendum for Calcitonin Gene-Related Peptide (CGRP) antagonists protocol	Approved	assisted treatment (MAT) products, a class that buprenorphine belongs. Dr. Marcus suggested that the Board should get more involved in reviewing the use of drug products without adequate follow up or prior medical claims. Dr. Barberio informed the Board that she is an X-wavered buprenorphine prescriber and her team follows up with their patients but many prescribers do not accept insurance hence the lack of medical claims in the State's records. The Board reviewed a proposed addendum for calcitonin gene-related peptide (CGRP) protocol that was approved in April 2019. The addendum incorporated recent guidelines published by the American Headache Society. Dr. Moynihan expressed concern about the various choices of migraine medications recommended to be used prior to the CGRPs. Dr. Swee expressed similar sentiments. The Board voted to recommend the protocol. Dr. Swee abstained.
New Business		
(A) Proposed protocol for Vimizim® (elosulfase)	Approved pending update of criterion #3	The Board reviewed a proposed protocol for elosulfase, a product indicated for the treatment of patients with Mucopolysaccharidosis type IVA also referred to as Morquio A syndrome. Dr. Swee was concerned that the Medication Exception Program (MEP) team will not be able to interpret the labs, tests requested as part of the criteria and suggested that it was unnecessary to include that criterion. Dr. Emenike explained that MEP already has such reviews in place through medical necessity forms and refers to literatures and guidelines to help them to interpret the tests or labs. Dr. Moynihan, a Rheumatologist, informed the Board that in her position as Medicare medical director for the west coast, they allow similar claims to go through without much scrutiny except for unusual situations. Mr. Currie, pharmacy director for Horizon said that for their plan, some of the requests in the protocols are more for validation that the drug therapy is working. Mr. Vaccaro supported Dr. Swee's suggestion for a progress note-based report where the prescriber will include results of some tests if necessary. The Board approved the protocol pending rewording of criterion #3.

October 28, 2020 DURB Meeting Summary (Draft)

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>(B) Proposed protocol for Naglazyme® (galsulfase)</td><td>Approved pending update of criterion #3</td><td>The Board reviewed a protocol for galsulfase, a product indicated for the treatment of patients with Mucopolysaccharidosis VI also called Maroteaux-Lamy syndrome. The discussion about the tests/labs criterion is also applicable to this protocol so the Board approved the protocol pending update of the criterion.</td></tr>
<tr><td>(C) Proposed protocol for Mepsevii® (vestronidase alfa-vjbk)</td><td>Approved pending update of criterion #3</td><td>The Board reviewed a protocol for vestronidase alfa-vjbk), a product indicated for the treatment of patients with Mucopolysaccharidosis VII also referred to as Sly syndrome. They approved the protocol with similar changes as the previous two.</td></tr>
<tr><td>Draft of DURB Annual Report for SFY 2020</td><td></td><td>The DURB annual report for SFY 2020 will be reviewed by board members and comments sent to the Secretary by November 30, 2020. Final version will be sent to DHS assistant commissioner for review, then on to the DHS and DOH commissioners for sign off.</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>The Board reviewed prior authorization (PA) denial report comparing all MCO plans including FFS for the 2nd quarter of 2020.
There were no comments regarding the report.
Percentage of prior authorization requests relative to total claims and denials associated with the PAs are listed below:

<table>
<tr><th>Plan</th><th>(%) PA Requests of claims</th><th>Denial (%)</th></tr>
<tr><td>FFS</td><td>0.5</td><td>12</td></tr>
<tr><td>Aetna</td><td>0.6</td><td>42</td></tr>
<tr><td>Amerigroup</td><td>1.2</td><td>30</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>41</td></tr>
<tr><td>UHC</td><td>0.6</td><td>53</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>39</td></tr>
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October 28, 2020 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>The Board reviewed a summary of actions from previous meetings (July 2019 thru July 2020).</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for July 2020 (FFS)/August 2020 (MCOs) was provided for review.

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>July 2020</td><td>$10,263,903</td><td>$10,933,902</td></tr>
<tr><td>MCOs</td><td>August 2020</td><td>$83,639,315</td><td>$119,672,681</td></tr>
</table></td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided a link to:
a. FAQs for Pharmacists on Naloxone Co-prescribing
b. metformin ER recall updates.</td></tr>
<tr><td>COVID-19 Drugs Utilization write up</td><td></td><td>The Board formed a subcommittee to work on a paper about the various drugs used relative to COVID-19 therapy. They will be reviewing the utilization of these products. The subcommittee will be made up of Dr. Swee, Dr. Marcus and Dr. Gooen.</td></tr>
<tr><td>Follow up items:</td><td></td><td>- United Healthcare will provide examples to explain their process for determining clinical criteria not met (CCNM) category (in 30 days)
- The Board's subcommittee work on COVID-19-related products.
- Update criterion #3 of the enzyme replacement products reviewed - Vimizim, Naglazyme, and Mepsevii.</td></tr>
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NEW JERSEY DRUG UTILIZATION REVIEW BOARD
QUAKERBRIDGE PLAZA, BUILDING 7, Rooms 200 ABC

January 20, 2021

Secretary's Report:

1. The Commissioners have signed off on the DURB annual report for SFY 2019. This is now published in the NJ Register

2. The Division is working with the Department to sign off on the protocols recommended by the Board at the July and October 2020 meetings. This includes the DURB annual report for SFY 2020

3. Carole Johnson, Commissioner of the New Jersey Department of Human Services, will depart the Murphy Administration as of January 15, 2021 to join the Biden-Harris Administration's White House COVID-19 response team

4. Dr. Linda Gooen no longer resides in NJ and has therefore resigned her position as a member of the NJ DURB

United Healthcare Report for Clinical Criteria Not Met Denials

January 2021

Summary of Examples:

Patient #	Date	Drug	Reasons for Denial
1	12.3.19	Advair	- No evidence patients has asthma - No evidence patient has tried or failed available generics AirDuo, Wixeda
2	10.2.19	Pimecrolimus Cream 1%	- Patient is not using for facial or groin area - No evidence patient has tried or failed one topical corticosteroid in the past 90 days
3	10.11.19	Diclofenac Gel 1%	- Patient did not demonstrate diagnosis of osteoarthritis of joints that can respond to topical treatment such as hands, knees, ankle, elbows, feet and wrists
4	12.18.19	Lansoprazole capsule 30mg DR	- Quantity requested is for pathological hypersecretory condition which patient does not have

Protocol for the Safe and Efficient Use of Opioids

Approved October 2018

Addendum: January 2021

1. Reduce maximum daily dose for opioid tolerant patients from 120 MME (morphine milligram equivalent) to 90 MME as recommended by the CDC (7)
2. Emphasize co-prescribing of naloxone under specified circumstances (8)

Exclusions

Cancer patients
Sickle cell patients
Hospice patients
Palliative or end of life care

All prescriptions for opioids will be approved based on the following criteria:

Short-acting opioids (SAOs)

1. All SAOs for acute pain (e.g. injury, minor surgery, dental procedure) in opioid naïve patients (defined as no opioid therapy in the previous 90 days) is limited to 5 days supply

2. Daily dose is not greater than **50 morphine milligram equivalents** (MME) for an opioid naïve patient or greater than 90 MME for an opioid tolerant patient. [medical necessity/rationale will be required]

3. Patient is being treated for moderate to severe pain (documentation associated with diagnosis/rationale will be required)

4. Patient has tried and failed or has an intolerance or contraindication to non-opioid analgesics (such as non-steroidal [NSAIDs], acetaminophen, anticonvulsants, antidepressants, etc.) [documentation will be required]

5. Patient is maintained on no more than two SAOs

6. Concomitant use of opioids and benzodiazepines **will require prior authorization**

7. Naloxone prescription is provided or offered to patient/patient's family or caretaker in the following situations:
   a. Patient is receiving opioids at a dose ≥ 50 MME per day
   b. Patient is on concurrent benzodiazepine (regardless of opioid dose)
   c. Patient has a history of overdose or substance use disorder

Long-acting opioids (LAOs)

1. Patient is currently on a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain; **OR**

2. Patient is transitioning from one long-acting opioid analgesic to another

3. Daily dose is not greater than **50 morphine milligram equivalents** (MME) for an opioid naïve patient or greater than **90 MME** for an opioid tolerant patient. [medical necessity/rationale will be required]

4. Patient is being treated for moderate to severe pain (documentation associated with diagnosis/rationale will be required)

5. Patient does not have any of the following:
   a. Significant respiratory depression
   b. Acute or severe bronchial asthma or hypercarbia
   c. Known or suspected paralytic ileus

6. LAOs are not used in as needed (PRN) analgesia

7. Patient is maintained on no more than two LAOs

8. Concomitant use of opioids and benzodiazepines **will require prior authorization**

9. Naloxone prescription is provided or offered to patient/patient's family or caretaker in the following situations:
   a. Patient is receiving opioids at a dose of ≥ 50 MME per day
   b. Patient is on concurrent benzodiazepine (regardless of opioid dose)
   c. Patient has a history of overdose or substance use disorder

References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. JAMA. 2016;315(15):1624–1645
3. Chung JW, Zeng Y, Wong TK. Drug therapy for the treatment of chronic nonspecific low back pain: systematic review and meta-analysis. Pain Physician 2013; 16(6): E685-704
4. Gandam VH, Chauhan G et al. Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis; BMJ 2017; 356 doi: https://doi.org/10.1136/bmj.j760
5. Coffin P, Behar E et al. Nonrandomized Intervention Study of Naloxone Coprescription for Primary Care Patients Receiving Long-Term Opioid Therapy for Pain. Ann Intern Med. 2016;165(4):245-252
6. CDC. CDC Guideline for Prescribing Opioids for Chronic Pain-United States, 2016. Recommendations and Reports/March 18, 2016/65(1) 1-49. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm accessed 6/4/2018 and erratum published March 25, 2016. https://www.cdc.gov/mmwr/volumes/65/wr/mm6511a6.htm?s_cid=mm6511a6_w.htm accessed 6/4/2018
7. Morbidity and Mortality Monthly Weekly Report. August 8, 2019. 68(31). Accessed online November 4, 2020 at: https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6831e1-H.pdf

8. Jones CM, et al. Naloxone Co-prescribing to Patients Receiving Prescription Opioids in the Medicare Part D Program, United States, 2016-2017. JAMA. 2019;322(5):462-464. doi:10.1001/jama.2019.7988. Accessed online November 4, 2020 at: https://jamanetwork.com/journals/jama/fullarticle/2740706?guestAccessKey=ba19c71e-ed3d-4aa3-9b99-43fe44035b94&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=080619

Proposed Protocol for pyrimethamine (Daraprim®)

January 2021

Criteria for approval:

A. Treatment of toxoplasmosis

1. Documentation or confirmed diagnosis of severe acquired toxoplasmosis, including toxoplasmic encephalitis
2. Prescribed by or in consultation with an infectious disease specialist
3. Documentation that pyrimethamine will be used in combination with sulfadiazine or clindamycin and leucovorin per guideline recommendation
4. For HIV/AIDS patients, documentation that patient has tried and failed or has contraindication to trimethoprim-sulfamethoxazole (TMP-SMX)

B. Primary prophylaxis for toxoplasmosis in HIV/AIDS

1. Documentation or confirmed diagnosis of HIV/AIDS
2. Prescribed by or in consultation with an infectious specialist or HIV specialist
3. Documentation that pyrimethamine will be used in combination with sulfadiazine or clindamycin and leucovorin per guideline recommendation
4. Patient has tested positive for Toxoplasmosis gondii IgG antibodies
5. Documentation that patient has CD4 count <100 cells/μL
6. Documentation that patient has tried and failed or has contraindication to trimethoprim-sulfamethoxazole (TMP-SMX)
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
8. Adherence to antiretroviral therapy as evidenced by pharmacy claims history or office notes

Continuation of Therapy:

1. Compliance to prescribed medication as evidenced by pharmacy claims history or office notes
2. Discontinue treatment once CD4 count >200 cells/μL for at least 3 months

References:

1. Daraprim [Packet Insert]. Vyera Pharmaceuticals, New York, NY. August 2017
2. Konstantinovic N, et al. Treatment of toxoplasmosis: Current options and future perspectives. Food and Waterborne Parasitology. 2019 Jun; 15. Accessed online on September 20, 2020 at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7033996/
3. Toxoplasmosis. Harvard Health Publications. Drugs.Com. Updated May 11, 2020. Accessed online on September 16, 2020 at: https://www.drugs.com/health-guide/toxoplasmosis.html
4. Clinical Pharmacology (online database). Tampa FL: Gold Standard Inc.: 2019. Updated periodically
5. Dunay IR, et al. Treatment of Toxoplasmosis: Historical Perspective, Animal Models, and Current Clinical Practice. Clinical Microbiology Reviews; 31(4). October, 2018. https://cmr.asm.org/content/cmr/31/4/e00057-17.full.pdf

Proposed Protocol for Increlex® (mecasermin)

January 2021

Background:

Increlex *is a recombinant insulin-like growth factor-1 (IGF-1) used as replacement therapy in patients with primary severe IGF-1 deficiency.*

Criteria for approval:

1. Patient is 2 years old or older
2. Patient has confirmed diagnosis of one of the following:
   a. Growth hormone (GH) gene deletion; **AND**
   b. Has developed neutralizing antibodies to GH; **OR**
   c. Severe primary IGF-1 deficiency (Primary IGFD)*
3. Medication is prescribed by or in consultation with an endocrinologist
4. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence
5. Weight must be received for drugs that have weight-based dosing.
6. Patient does not have any contraindications to therapy such as:
   a. Closed epiphyses
   b. Pediatric patients with malignant neoplasia or a history of malignancy

*Severe primary IGF-1 deficiency is defined by:
a. Height standard deviation score $\leq$ -3.0
b. Basal IGF-1 standard deviation score $\leq$ -3.0
c. Normal or elevated growth hormone (GH)

References:

1. Increlex [package insert]. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. 12/2019
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Grimberg A, DiVall S, Polychronakos C, et al. On behalf of the Drug and Therapeutics Committee and Ethics Committee of the Pediatric Endocrine Society. Guidelines for Growth Hormone and Insulin Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr Nov 2016; 86: 361–397.
4. Cohen, J., Blethen, S., Kuntze, J., Smith, S. L., Lomax, K. G., & Mathew, P. M. (2014). Managing the Child with Severe Primary Insulin-Like Growth Factor-1 Deficiency (IGFD): IGFD Diagnosis and Management. Drugs in R&D, 14(1), 25–29. http://doi.org/10.1007/s40268- 014-0039-7

Proposed Protocol Exclusion for Victoza® (liraglutide)

January 2021

Background:

Victoza *is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated:*

1. *As an adjunct therapy to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus*

2. *To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease*

Criteria for approval:

1. Victoza will be approved for all FDA listed indications
2. Victoza is not approvable with concurrent administration of GLP-1 (glucagon-like peptide-1) agonists (e.g., Saxenda, Byetta, Trulicity, etc.)

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

Limitations:

1. Dose greater than 1.8mg per day

2. Prescription is for weight loss

FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of Victoza outweigh the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis

References:

1. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; August 2020.
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Garvey, WT et al. Efficacy and Safety of Liraglutide 3.0 mg in Individuals With Overweight or Obesity and Type 2 Diabetes Treated With Basal Insulin: The SCALE Insulin Randomized Controlled Trial. Diabetes Care 2020;43:1085–1093. Accessed online December 21, 2020 at: https://care.diabetesjournals.org/content/diacare/43/5/1085.full.pdf
4. Whitten, JS. Liraglutide (Saxenda) for Weight Loss. American Family Physician; 2016 Jul 15;94(2):161-166. Accessed online December 21, 2020 at: https://www.aafp.org/afp/2016/0715/p161.html

3rd Quarter 2020 (July - September) Prior Authorization Denial Report

	FFS	Aetna	Amerigroup	Horizon	UHC	Wellcare
Total # of Enrolled Beneficiaries (September 2020)	**70,518**	**99,896**	**228,700**	**976,879**	**380,625**	**96,167**
Total # of Pharmacy Claims Processed	**1,325,676**	**436,202**	**511,076**	**3,078,854**	**990,300**	**299,160**
Total Prior Authorizations (PA) Requests	**6,997 (0.5%)**	**2,846 (0.7%)**	**6,123(0.5%)**	**24,835 (0.8%)**	**8,327 (0.8%)**	**2,270 (0.8%)**
Denials	**890 (13%)**	**1,257 (44%)**	**2,237 (37%)**	**10,880 (44%)**	**4,183 (50%)**	**1,032 (45%)**
Breakdown of Denials*	**Totals**					
a. Clinical Criteria Not Met	215	1,121	2,174	2,338	887	762
b. Directed Intervention		1		146a		22
Age Standard Exceeded						
First Fill	63					
c. Drug-Drug Interaction/Conflict	16	1				
d. Duration Exceeded	7	7				386
e. Early/Same Day refill	59					
f. Excessive Dose	41	10		103	222	386
g. Incomplete Information	15	51		3,841	213	23
h. Incorrect Day Supply	197					
i. Incorrect DOB/ID	17					
j. Mandatory Generic	27	15		80		23
k. Prescriber Decreased Dose	3					
l. Prescriber Denies Rx	1					
m. Med Discontinued by Prescriber	25					
n. Medicare Part D Wraparound						
o. Methadone Maintenance	2					
p. MNF Not Returned by Prescriber	23					
q. Multiple Pharmacies						
r. Multiple Prescribers						
s. No Diagnosis Provided						
t. No Suboxone Waiver Number	1					
u. OTC alternative available	2					
v. Prescriber Changed to OTC Product	3					
w. Therapeutic Duplication	173	5				
x. Unacceptable Diagnosis		46				
y. Other			51			270
z. Non-formulary				4,272	2,746	
aa. Non-covered benefit				246	115	
TOTAL DENIALS	**890**	**1,257**	**2,237**	**10,880 b**	**4,183 b**	**1,872 b**

* See attachment for explanation of categories for FFS

** Denial letters are not sent to the prescriber for FFS

*** Directed intervention includes denied with formulary alternatives

a. Not included in Denial Totals

b. Breakdown of total denials may exceed the total number of absolute denials due to authorization requests resulting in more than 1 captured denial category.

Explanation of Denial Categories

Category	Explanation	Example/Comment
Age Standard Exceeded	Patient's age does not meet criteria approved by the DURB	
APAP Dose Exceeded	Self explanatory	
Clinical Criteria Not Met	Claim does not meet criteria set by the DURB	Drug written for indication not approved by the DURB
Daily Quantity Exceeded	Quantity limits established by DURB exceeded	
Drug-Drug Interaction	Self explanatory	
Duration Exceeded	Duration limit established by DURB exceeded	Could be extended with provider's justifiable clinical request
Early/Same Day Refill	Self explanatory	
Excessive Dose	Dose exceeds reasonable therapeutic recommendation	
First Fill	First fill of HIV medications or high dose opioids	Labs are required for HIV medications. Prescribers are contacted for opioid naïve patients.
Incomplete Information	Prescriber did not provide requested information	Diagnosis/ICD-9, Lab values, Ht, Wt, e.t.c.
Incorrect Day Supply	Self explanatory	Ex. Fosamax 4 tabs for 4 days rather than 30.
Incorrect DOB/ID	Pharmacy has submitted claim using the wrong DOB or beneficiary ID#	
Mandatory Generic	Brand name requested without reasonable /clinical justification	Side effects with generic is a reason for exemption
Med Discontinued by Prescriber	Self explanatory	- change in therapy - Hgb >12.0 for ESA; provider denies refill request by pharmacy
Medicare Part D Wraparound	Paid for by Part D insurance if not on table	State provides 6-day window for appeal process
Methadone Maintenance	Request for narcotic/BNDZ for patient on MMT from another physician other than primary care giver	
MNF Not Returned by Prescriber	Prescriber did not return form with clinical or verification information required for continuation of therapy	- duplicate therapy by same prescriber - lab values, height/weight when required
Multiple Pharmacies	Patient presents script for similar drug to different pharmacies	"Pharmacy shoppers"
Multiple Prescribers	Patient goes to multiple providers for the same drug or similar drugs	"Doctor shoppers"
No Diagnosis Provided	Prescriber did not provide diagnosis required as part of approval criteria	Verification of diagnosis from prescriber's office will suffice.
No Suboxone Waiver #	Self explanatory	
No Verification	Prescriber did not confirm writing the prescription.	
OTC alternative available	Part of State FY 2010 Budget initiative – Prescription drug product not covered if OTC alternative is available.	- Medication is prescribed for symptomatic relief of cough and cold - OTC equivalent available
Prescriber Changed to OTC Product	Prescriber changed from prescription brand to OTC brand	- PPIs initiative - Non-sedating antihistamines initiative - Ophthalmic drops conversion initiative
Prescriber Decreased Dose	Self explanatory	Decrease from BID to QD dosing
Prescriber Denies RX	Prescriber denies writing prescription	Could be wrong info from pharmacy or fraud
Retinoid/Topical	Prescription used for cosmetic purposes	
Therapeutic Duplication	Requested drug belongs to the same therapeutic class as one on profile	Aciphex® and Nexium®
Unacceptable Diagnosis	Diagnosis provided does not meet criteria approved by the DURB	Some flexibility allowed with prescriber's input

Summary of DURB Recommendations

January 20, 2021

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
October 2020	Addendum to calcitonin-related peptide (CGRP) antagonists products protocol	- The Board recommended the approval of the addendum previously approved in April 2019	
	Protocol for Vimizim (elosulfase)	- The Board recommended the approval of the protocol with a request to modify the wording of criterion #3 (tests required for approval)	This criterion will be reworded
	Protocol for Naglazyme (galsulfase)	- The Board recommended the approval of the protocol with a request to modify the wording of criterion #3 (tests required for approval)	This criterion will be reworded
	Protocol for Mepsevii (vestronidase alfa-vjbk)	- The Board recommended the approval of the protocol with a request to modify the wording of criterion #3 (tests required for approval)	This criterion will be reworded
July 2020	Protocol for Varubi (rolapitant)	- The Board recommended the approval of the protocol	
	Protocol for Vyondys 53 (golodirsen)	- The Board recommended the approval of the protocol	
	Protocol for Cryopyrin-associated periodic syndromes (CAPS) products	- The Board recommended approval of the protocol after including a language that allows for off-label use	This update will be included in the body of the protocol
	Protocol for Spravato (esketamine)	- The Board recommended approval of the protocol after changing the step therapy requirement from 4 weeks each to 3 weeks each	This update will be included in the body of the protocol
			The Division is working with the Department to move forward outstanding requests for approval by the Commissioner. Protocols recommended by the Board from July 2019 through July 2020 are under consideration, as well as the DURB Annual Report for 2019.

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Summary of DURB Recommendations

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
			Protocols recommended by the Board are listed within the "Summary of DURB Actions" found on the NJ DURB website.
January 2020	Protocol for Fabry disease products	- The Board recommended the approval of the protocol	
	Protocol for Lambert-Eaton Myasthenic Syndrome (LEMS) products	- The Board recommended the approval of the protocol	
	Protocol for Strensiq® (asfotase)	- The Board recommended the approval of the protocol	
October 2019	Protocol for hereditary transthyretin-mediated amyloidosis (hATTR)	- The Board recommended the approval of the protocol with addition of the requirement for prescription to be written by or in consultation with a specialist in the treatment of aTTR	This update will be included in the final copy of the protocol
	Protocol for Elaprase® (idursulfase)	- The Board recommended the approval of the protocol	
	Protocol for Gaucher disease products	- The Board recommended the approval of the protocol with a change: delete the criterion that requires a patient to be intolerant to enzyme replacement therapy to qualify for substrate replacement therapy	This update will be included in the final copy of the protocol
	Protocol for Cablivi® (caplacizumab-yhdp)	- The Board recommended the approval of the protocol	

2.

Protocol for the Safe and Efficient Use of Opioids

Approved October 2018

Exclusions
Cancer patients
Sickle cell patients
Hospice patients
Palliative or end of life care

All prescriptions for opioids will be approved based on the following criteria:

Short-acting opioids (SAOs)

1. All SAOs for acute pain (e.g. injury, minor surgery, dental procedure) in opioid naïve patients (defined as no opioid therapy in the previous 90 days) is limited to 5 days supply
2. Daily dose is not greater than **50 morphine milligram equivalents** (MME) for an opioid naïve patient or greater than 120 MME for an opioid tolerant patient. [medical necessity/rationale will be required]
3. Patient is being treated for moderate to severe pain (documentation associated with diagnosis/rationale will be required)
4. Patient has tried and failed or has an intolerance or contraindication to non-opioid analgesics (such as non-steroidal [NSAIDs], acetaminophen, anticonvulsants, antidepressants, etc.) [documentation will be required]
5. Patient is maintained on no more than two SAOs
6. Concomitant use of opioids and benzodiazepines **will require prior authorization**
7. Naloxone prescription is provided or offered to patient/patient's family or caretaker for opioid/benzodiazepine combinations

Long-acting opioids (LAOs)

1. Patient is currently on a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain; **OR**

2. Patient is transitioning from one long-acting opioid analgesic to another

3. Daily dose is not greater than **50 morphine milligram equivalents** (MME) for an opioid naïve patient or greater than 120 MME for an opioid tolerant patient. [medical necessity/rationale will be required]

4. Patient is being treated for moderate to severe pain (documentation associated with diagnosis/rationale will be required)

5. Patient does not have any of the following:
   a. Significant respiratory depression
   b. Acute or severe bronchial asthma or hypercarbia
   c. Known or suspected paralytic ileus

6. LAOs are not used in as needed (PRN) analgesia

7. Patient is maintained on no more than two LAOs

8. Concomitant use of opioids and benzodiazepines **will require prior authorization**

9. Naloxone prescription is provided or offered to patient/patient's family or caretaker for opioid/benzodiazepine combinations

References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. JAMA. 2016;315(15):1624–1645
3. Chung JW, Zeng Y, Wong TK. Drug therapy for the treatment of chronic nonspecific low back pain: systematic review and meta-analysis. Pain Physician 2013; 16(6): E685-704
4. Gandam VH, Chauhan G et al. Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis; BMJ 2017; 356 doi: https://doi.org/10.1136/bmj.j760
5. Coffin P, Behar E et al. Nonrandomized Intervention Study of Naloxone Coprescription for Primary Care Patients Receiving Long-Term Opioid Therapy for Pain. Ann Intern Med. 2016;165(4):245-252
6. CDC. CDC Guideline for Prescribing Opioids for Chronic Pain-United States, 2016. Recommendations and Reports/March 18, 2016/65(1) 1-49. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm accessed 6/4/2018 and erratum published March 25, 2016. https://www.cdc.gov/mmwr/volumes/65/wr/mm6511a6.htm?s_cid=mm6511a6_w.htm accessed 6/4/2018

Protocol for Vimizim® (elosulfase alfa)

Approved October 2020

Background:
Mucopolysaccharidosis (MPS) IVA or Morquio A syndrome is an autosomal recessive lysosomal storage disorder (LSD) caused by deficiency of the N-acetylgalactosamine-6-sulfatase (GALNS) enzyme, which impairs lysosomal degradation of keratan sulphate and chondroitin-6-sulphate.

***Vimizim** is a hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)*

Criteria for approval:

1. Patient has a diagnosis of Mucopolysaccharidosis IV type A (MPS IVA, Morquio A syndrome); **AND**

2. Diagnosis has been confirmed by one of the following:
   a. Genetic testing; **OR**
   b. Absence or deficiency in N-acetylgalactosamine 6-sulfatase (GALNS) enzyme activity; **AND**
3. Progress notes indicating progressive improvement with treatment (for example distance walked in six minutes [6-MWT], etc.), compared to baseline testing and/or clinical assessments to assess response to therapy will be required; **AND**

4. Documented clinical signs and symptoms of Morquio A syndrome (e.g., kyphoscoliosis, pectus carinatum, knee deformity, etc.)

5. Patient does not have any contraindication(s) to the requested medication; **AND**

6. Medication is being prescribed by or in consultation with an endocrinologist, geneticist, metabolic disorders specialist, or an expert in the disease state; **AND**

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

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

9. Vimizim will be administered under the supervision of a healthcare professional with the capability to manage anaphylaxis.

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Continuation of therapy:

1. Progress notes indicating progressive improvement with treatment (for example distance walked in six minutes [6-MWT], etc.), compared to baseline testing and/or clinical assessments to assess response to therapy will be required; **AND**

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; **AND**

3. For dose increase requests, weight must be received for drugs that have weight-based dosing.

Note: Vimizim has a black box warning:

Life-threatening anaphylactic reactions have occurred in some patients during Vimizim infusions. Anaphylaxis, presenting as cough, erythema, throat tightness, urticaria, flushing, cyanosis, hypotension, rash, dyspnea, chest discomfort, and gastrointestinal symptoms in conjunction with urticaria, have been reported to occur during infusions, regardless of duration of the course of treatment.

Closely observe patients during and after Vimizim administration and be prepared to manage anaphylaxis.

Patients with acute respiratory illness may be at risk of serious acute exacerbation of their respiratory compromise due to hypersensitivity reactions, and require additional monitoring

References:

1. Vimizim [Product information]. BioMarin Pharmaceutical Inc. Novato, CA; 12/2019.
2. Jones S, et al. Mucopolysaccharidoses: Clinical features and diagnosis. UpToDate. From: https://www.uptodate.com (Accessed on May 6, 2020.)
3. Genetics Home Reference. U.S. National Library of Medicine. Mucopolysaccharidosis type IV. From: https://ghr.nlm.nih.gov/condition/mucopolysaccharidosis-type-iv (Accessed on May 6, 2020)
4. Vimizim [Website]. BioMarin Pharmaceutical Inc. From: https://www.vimizim.com/about-vimizim/how-vimizim-can-help. (Accessed on May 6, 2020).
5. Akyol MU et al. Recommendations for the management of MPS IVA: systematic evidence- and consensus-based guidance. Orphanet Journal of Rare Diseases volume 14: 137. 2019. (Accessed on August 26, 2020)
6. National Organization for Rare Disorders. Mucopolysaccharidosis IV. Available at: https://rarediseases.org/rare-diseases/morquio-syndrome/ (Accessed on September 18, 2020)

Protocol for Naglazyme® (galsulfase)

Approved October 2020

Background:
Mucopolysaccharidosis VI (MPS VI) is a very rare autosomal recessive disorder caused by mutations in the arylsulfatase B (ARSB) gene, which lead to deficient activity of the lysosomal enzyme ASB. This enzyme is important for the breakdown of the glycosaminoglycans (GAGs) dermatan sulfate and chondroitin sulfate, which accumulate in body tissues and organs of MPS VI patients.

***Naglazyme** is indicated for patients with Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome).*

Criteria for approval:

1. Patient has a diagnosis of Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome); **AND**

2. Diagnosis has been confirmed by one of the following:
    a. Detection of mutations in the arylsulfatase B (ARSB) gene
    b. Absence or deficient activity of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) in leukocytes or fibroblasts; **AND**

3. Progress notes indicating progressive improvement with treatment (for example distance walked in six minutes [6-MWT], etc.), compared to baseline testing and/or clinical assessments to assess response to therapy will be required; **AND**

4. Documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, pectus carinatum, gait disturbance, reduced pulmonary function, etc.)

5. Patient does not have any contraindication(s) to the requested medication; **AND**

6. Medication is being prescribed by or in consultation with an endocrinologist, geneticist, metabolic disorders specialist, or an expert in the disease state; **AND**

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

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

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Continuation of therapy:

1. Progress notes indicating progressive improvement with treatment (for example distance walked in six minutes [6-MWT], etc.), compared to baseline testing and/or clinical assessments to assess response to therapy will be required; **AND**

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; **AND**

3. For dose increase requests, weight must be received for drugs that have weight-based dosing.

References:

1. Naglazyme [Product information]. BioMarin Pharmaceutical Inc. Novato, CA; 12/2019.
2. Jones S, et al. Mucopolysaccharidoses: Clinical features and diagnosis. UpToDate. From: https://www.uptodate.com (Accessed on May 5, 2020.)
3. Giugliani R, Harmatz P, Wraith JE. Management guidelines for mucopolysaccharidosis VI. Pediatrics. 2007;120:405-418
4. Giugliani, R, Lampe, C, Guffon, N. Natural history and galsulfase treatment in mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome) – 10-year follow-up of patients who previously participated in an MPS VI survey study. Am J Med Genet A. 2014;164A(8):1953–1964.
5. Akyol, M.U., Alden, T.D., Amartino, H. et al. Recommendations for the management of MPS VI: systematic evidence- and consensus-based guidance. Orphanet J Rare Dis 14, 118 (2019). https://doi.org/10.1186/s13023-019-1080-y
6. Dafne D G Horovitz , Tatiana S P C Magalhães, Angelina Acosta, et al. Enzyme replacement therapy with galsulfase in 34 children younger than five years of age with MPS VI. Mol Genet Metab. 2013 May;109(1):62-9. doi: 10.1016/j.ymgme.2013.02.014. Epub 2013 Mar 5.
7. Vairo F et al. Diagnostic and treatment strategies in mucopolysaccharidosis VI. Appl Clin Genet. 2015; 8: 245–255.

Protocol for Mepsevii® (vestronidase alfa-vjbk)

Approved October 2020

Background:
Mucopolysaccharidosis VII (MPS VII, Sly syndrome) is caused by mutations in the gene encoding the beta-glucuronidase (GUS) enzyme, located on chromosome 7q11.21. Beta-glucuronidase enzyme deficiency causes glycosaminoglycans (GAGs) to accumulate in cells throughout the body. Vestronidase alfa is a recombinant human lysosomal beta glucuronidase intended to provide exogenous GUS enzyme for uptake into cellular lysosomes.

***Mepsevii** is a recombinant human lysosomal beta glucuronidase indicated in pediatric and adult patients for the treatment of Mucopolysaccharidosis VII (MPS VII, Sly syndrome).*

Criteria for approval:

1. Patient has a documented diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome); **AND**

2. Diagnosis has been confirmed by one of the following:
    a. Detection of mutations in the beta-glucuronidase (GUSB) gene
    b. Beta-glucuronidase (GUS) enzyme deficiency in peripheral blood leukocytes or fibroblasts; **AND**

3. Progress notes indicating progressive improvement with treatment (for example distance walked in six minutes [6-MWT], etc.), compared to baseline testing and/or clinical assessments to assess response to therapy will be required; **AND**

4. Patient does not have any contraindication(s) to the requested medication; **AND**

5. Medication is being prescribed by or in consultation with an endocrinologist, geneticist, metabolic disorders specialist, or an expert in the disease state; **AND**

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; **AND**

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

8. Mepsevii will be administered under the supervision of a healthcare professional with the capability to manage anaphylaxis.

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Continuation of therapy:

1. Progress notes indicating progressive improvement with treatment (for example distance walked in six minutes [6-MWT], etc.), compared to baseline testing and/or clinical assessments to assess response to therapy will be required; **AND**

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; **AND**

3. For dose increase requests, weight must be received for drugs that have weight-based dosing.

Note: Mepsevii has a black box warning:
Anaphylaxis has occurred with MEPSEVII administration, as early as the first dose, therefore appropriate medical support should be readily available when MEPSEVII is administered.
• Closely observe patients during and for 60 minutes after MEPSEVII infusion
• Immediately discontinue the MEPSEVII infusion if the patient experiences anaphylaxis

References:

1. Mepsevii [Product information]. Ultragenyx Pharmaceutical Inc. Novato, CA; 12/2019.
2. "Mucopolysaccharidosis Type VII." NORD (National Organization for Rare Disorders), rarediseases.org/rare-diseases/sly-syndrome/.
3. "Mucopolysaccharidosis Type VII | Genetic And Rare Diseases Information Center (GARD) – An NCATS Program". Rarediseases.Info.Nih.Gov, 2019, https://rarediseases.info.nih.gov/diseases/7096/mucopolysaccharidosis-type-vii. Accessed 20 June 2020..
4. Clinicaltrials.gov. A Phase 3 Study of UX003 Recombinant Human Betaglucuronidase (rhGUS) Enzyme Replacement Therapy in Patients With Mucopolysaccharidosis Type 7 (MPS 7). NCT02230566. Available at: https://clinicaltrials.gov/ct2/show/NCT02230566
5. Clinicaltrials.gov. An Open-Label Phase 1/2 Study to Assess the Safety, Efficacy and Dose of Study Drug UX003 Recombinant Human Beta-glucuronidase (rhGUS) Enzyme Replacement Therapy in Patients With Mucopolysaccharidosis Type 7 (MPS 7). NCT01856218. Available at: https://clinicaltrials.gov/ct2/show/NCT01856218
6. National MPS Society. A guide to understanding MPS VII. Available at https://mpssociety.org/cms/wp-content/uploads/2017/04/MPS_VII_2008.pdf

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