

Summary of DURB Recommendations

January 25, 2023

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
October 2022	<p>Addendum to calcitonin gene-related peptide (CGRP) receptor antagonist protocol</p> <p>Proposed protocol for glucagon-like peptide-1 receptor agonists for T2D</p> <p>Proposed protocol for biologics in moderate to severe asthma treatment</p> <p>Proposed protocol for Cholbam (cholic acid)</p> <p>Proposed protocol for Crysvisa (burosumab-twza)</p>	<ul style="list-style-type: none"> - The Board recommended the protocol - The Board recommended the protocol with suggestions to reword criterion #3 and removal of criterion #1 under continuation of therapy - The Board recommended the protocol - The Board recommended the protocol with suggestion to remove the monitoring requirement in the “continuation of therapy” section - The Board recommended the protocol 	<p>An updated version will be presented at the next meeting</p> <p>An updated version will be presented at the next meeting</p>
July 2022	<p>Addendum to calcitonin gene-related peptide (CGRP) receptor antagonist protocol</p> <p>Proposed protocol for Vuity® (pilocarpine ophthalmic)</p> <p>Proposed protocol for complement inhibitor products (Soliris®, Empaveli®, Ultomiris®)</p> <p>Proposed protocol for Bylvay® (odevixibat)</p>	<ul style="list-style-type: none"> - The Board tabled the protocol with a suggestion to create a flow chart that will make it easier to understand - The Board recommended the protocol with a suggestion to add optometrist to criterion #3 - 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 - The Board recommended the protocol with a suggestion to add “if able to report” to criterion #3 	<p>An updated version will be presented at the next meeting</p> <p>An updated version will be presented at the next meeting</p> <p>An updated version will be presented at the next meeting</p>
April 2022	<p>Proposed protocol for Hetlioz® (tasimelteon)</p> <p>Proposed protocol for cysteamine products (Cystagon® and Procysbi®)</p> <p>Proposed protocol for Revcovi® (elapegademase)</p> <p>Proposed protocol for Luxturna® (voretigene neparvovec-rzyl)</p>	<ul style="list-style-type: none"> - The Board wanted more information about why young teens couldn’t use pills and why teens and adults couldn’t use the liquid - The Board recommended the protocol - The Board recommended the protocol - The Board recommended the protocol 	<p>This information will be presented at the next meeting</p>

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January 2022	Addendum for proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor products protocol	- The Board recommended the addendum to the protocol	An updated version was presented and approved at the following meeting. An updated version was presented and approved at the following meeting. An updated version was presented and approved at the following meeting.
	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	
	Proposed protocol for nitisinone products	- The Board recommended the protocol with suggestions to reword criteria #4 and #6	
	Proposed protocol for Lucemyra® (lofexidine)	- The Board recommended the protocol with suggestions to criterion #4 and delete criterion #5	
	Proposed protocol for Paxlovid® (nirmatrelvir/ritonavir)	- The Board approved the protocol	
	Proposed protocol for molnupiravir	- The Board approved the protocol	