

Summary of DURB Recommendations

October 17, 2024

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
July 2024	<p>Proposed addendum to the protocol for Dupixent (dupilumab)</p> <p>Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitors</p> <p>Proposed addendum to the protocol for Vyjuvek (beremagene geperpavec)</p> <p>Proposed addendum to the protocol for Duchenne Muscular Dystrophy products</p> <p>Proposed protocol for Qelbree (viloxazine)</p> <p>Proposed protocol for Wegovy to reduce the risk of major adverse cardiovascular events (MACE)</p>	<ul style="list-style-type: none"> <li>- The Board recommended the addendum to the protocol</li> <li>- The Board recommended the addendum to the protocol</li> <li>- The Board recommended the addendum to the protocol</li> <li>- The Board recommended the protocol with suggested changes to:                             <ul style="list-style-type: none"> <li>- Criterion #5 to read: Medication is prescribed by or in consultation with a pediatric/adult neurologist, or a specialist who is an expert in the treatment of DMD and other neuromuscular disorders</li> <li>- Same as above for criterion #4 in the continuation of therapy section</li> <li>- Delete criterion #4 in the continuation of therapy section which referred to making patient's weight available</li> </ul> </li> <li>- The Board recommended the protocol with suggested change to:                             <ul style="list-style-type: none"> <li>a. Delete criterion #3 which required treatment failure with atomoxetine, clonidine, or guanfacine</li> </ul> </li> <li>- The Board recommended the protocol</li> </ul>	<p>These changes will be made and presented at the next meeting</p> <p>This change will be made and presented at the next meeting</p>
April 2024	<p>Proposed protocol for Ingrezza® (valbenazine)</p> <p>Proposed protocol for Egrifta® (tesamorelin)</p> <p>Proposed addendum to the protocol for Spinal Muscular Atrophy (SMA) products</p> <p>Proposed addendum to the protocol for Direct Acting Antivirals (for hepatitis C) products</p>	<ul style="list-style-type: none"> <li>- The Board recommended the protocol</li> <li>- The Board recommended the protocol with suggested change to delete criterion #4c (waist circumference)</li> <li>- The Board recommended the addendum to the protocol</li> <li>- The Board recommended the protocol suggested change to criterion #B3 to read: Provide previous treatment history including medication, length of therapy, and whether the patient is a relapser, noncompliant, or reinfected</li> </ul>	<p>Updated information was presented at the next meeting</p> <p>Updated information was presented at the next meeting</p>

Summary of DURB Recommendations

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
	Proposed addendum to Zurzuvae (zuranolone) protocol	<ul style="list-style-type: none"> <li>- The Board recommended the protocol with suggestion to change criterion #3 to read: Medication is prescribed by or in consultation with an appropriate healthcare provider with planned follow up.</li> </ul>	Updated information was presented at the next meeting
January 2024	<p>Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitor products</p> <p>Proposed addendum to the protocol for proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor products</p> <p>Proposed update to the protocol for Synagis (palivizumab)</p> <p>Proposed addendum to the protocol for Lumizyme (alglucosidase alfa) for Pompe disease</p> <p>Proposed protocol for Zurzuvae (zuranolone)</p>	<ul style="list-style-type: none"> <li>- The Board recommended the protocol</li> <li>- The Board recommended the protocol with suggested changes to criterion #3 for initial approval and criterion #4 for subsequent requests.</li> <li>- The Board recommended the protocol</li> <li>- The Board recommended the protocol</li> <li>- The Board recommended the protocol with suggested changes to criteria #1, 2, 4 for initial approval and criterion #2 in continuation of therapy section</li> </ul>	<p>Updated information was presented at the next meeting</p> <p>Updated information was presented at the next meeting</p>
October 2023	<p>Proposed addendum to biologic receptor modifiers (BRMs) protocol for plaque psoriasis</p> <p>Proposed protocol for Kanuma (sebelipase alfa)</p> <p>Proposed protocol for Vyjuvek (beremagene geperpavec)</p> <p>Proposed addendum to Duchenne muscular dystrophy products protocol</p>	<ul style="list-style-type: none"> <li>- The Board recommended the protocol</li> <li>- The Board recommended the protocol</li> <li>- The Board recommended the protocol with suggested changes to criterion #5</li> <li>- The Board recommended the protocol with suggested changes to criteria # 2, 6 and 10</li> </ul>	<p>The updated information was presented at the next meeting</p> <p>The updated information was presented at the next meeting</p>