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Drug Utilization Review Board
1100 East William Street, Suite 101
Carson City, Nevada 89701

Re: Public Comment for January 27, 2022 DURB Meeting

Dear DURB Meeting Coordinator,

We submit this public comment on behalf of Vanda Pharmaceuticals Inc. ("Vanda") and for the benefit of the Nevada Medicaid patients with Non-24-Hour Sleep-Wake Disorder ("Non-24") or nighttime sleep disturbances from Smith-Magenis Syndrome ("SMS") who have been denied prescription drug coverage for Hetlioz based on Nevada Medicaid's unlawful criteria permitting coverage only for Non-24 patients who are totally blind. The current criteria are inconsistent with Hetlioz's FDA-approved label and the federal Medicaid Act. We request that the Drug Utilization Review Board ("DURB") reevaluate its Hetlioz criteria, eliminate the blindness requirement for Non-24, and provide for coverage of Hetlioz's FDA-approved SMS indication.

The DURB last reviewed Hetlioz on January 28, 2016, when it stated that Hetlioz approval will be granted if, among other things, "[t]he recipient is totally blind."[1] However, FDA has approved Hetlioz to treat *all* individuals with Non-24 without regard to whether they are blind, and the Hetlioz indication for use does not include *any* reference to blindness.[2] Indeed, FDA has explicitly stated that its approval for Hetlioz extends to Non-24 patients who are not blind.[3] Respectfully, Nevada Medicaid's requirement of blindness is plainly inconsistent with Hetlioz's FDA-approved label and must be eliminated. This is especially important because Hetlioz remains the *only* FDA-approved treatment for Non-24.

In addition, on December 1, 2020, FDA approved Hetlioz for the treatment of nighttime sleep disturbances in SMS patients. As with Non-24, Hetlioz is the first and *only* FDA approved treatment for

[1] https://dhcfp.nv.gov/uploadedFiles/dhcfpnvgov/content/Resources/AdminSupport/Manuals/MSM/C1200/MSM_1200_18_07_02(1).pdf.
[2] HETLIOZ® (tasimelteon) package insert (October 2019), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/205677s006lbl.pdf.
[3] In response to a Citizen Petition, FDA clarified that it considers use in Non-24 patients who are not completely blind to be within HETLIOZ®'s FDA-approved indication for use and that "the benefits of Hetlioz therapy are not limited to those Non-24 patients who are totally blind." U.S. Food and Drug Administration, Response to Citizen Petition (Docket No. 2015-P-2142) (Jan. 27, 2020), https://downloads.regulations.gov/FDA-2015-P-2142-0006/attachment_1.pdf., at 5-7.

patients with SMS, a rare genetic disorder characterized by significant sleep disturbances, among other things. Since that time, Nevada Medicaid has not updated its clinical parameters for coverage of Hetlioz to include SMS and the criteria today cover only Non-24.

The Medicaid Act requires that state Medicaid plans cover both medically necessary drugs and all FDA-approved drugs that are covered by a rebate agreement between the drug manufacturer and the federal government, as Hetlioz is. 42 U.S.C. §§ 1396a(a)(8), 1396a(a)(10)(A), 1396r-8. It further requires that states make available to all categorically needy individuals the same amount, scope, and duration of services it makes available to any other categorically needy individuals. *Id.* § 1396a(a)(10)(B). Therefore, it is unlawful under the Act to require blindness in Hetlioz prescribing criteria because doing so denies these statutory guarantees to sighted Medicaid patients with Non-24. It is also unlawful to exclude coverage for SMS.

When presented similar information, Colorado recently revised its Medicaid prior authorization criteria for Hetlioz to remove the requirement that a Medicaid enrollee with Non-24 must be blind and to include coverage for SMS.[4] Colorado's revision followed a lawsuit we filed in federal court on behalf of a sighted Medicaid patient who was denied Hetlioz coverage under the state's blindness requirement. (Attachment A.) Colorado also stipulated that it approved the plaintiff's request for Hetlioz coverage as medically necessary. (Attachment B.) And in the past two weeks, Iowa, North Carolina, Pennsylvania, Ohio, and Michigan all updated their Hetlioz Medicaid prior authorization criteria to conform with the Medicaid Act.

We appreciate your attention to this request and would be happy to discuss and or provide any additional information for your consideration.

Sincerely,

Paul W. Hughes

[4] https://hcpf.colorado.gov/sites/hcpf/files/Appendix%20P%2001.01.22%20V2.pdf.