



Sent via electronic mail

September 24, 2020

Preeya Noronha Pinto, Partner
David J. Farber, Partner
King & Spalding LLP
Suite 200
Washington, D.C. 20006-4707

Stephan Barbera
Vice President, Market Access
UroGen Pharma
400 Alexander Park Dr., 4th Floor
Princeton, NJ 08540

Re: QUIC Form 202005 JELMYTO™

Dear Ms. Pinto, Mr. Farber, and Mr. Barbera:

This letter is in response to the correspondence, dated September 21, 2020, sent to Terry Fortin, Assistant Senior Manager, National Council for Prescription Drug Programs (NCPDP) regarding QUIC Form 202005 for JELMYTO™ submitted to NCPDP from UroGen Pharm, Inc.

NCPDP is a not-for-profit, ANSI-Accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI accredited standards, and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP creates the standards that facilitate the interchange of data amongst pharmacies, physicians, pharmacy benefits managers, payers, processors and manufacturers. The NCPDP Billing Unit Standard (BUS) provides guidelines for consistent implementation of drug/product packaging for use in all applicable NCPDP Standards. NCPDP's Work Group 2 (WG2) Product Identification is responsible for maintaining this Standard.

On September 22, 2020, the WG2 Product Review and Billing Unit Exception Task Group completed its discussion of the QUIC form. Following UroGen's presentation during the August 25th call and a closer examination of the product insert, the task group members understand the Hydrogel is a key clinical component to the absorption and release of Mitomycin in the kidney, pelvis and calyces and does not simply dilute or buffer.

The task group agreed the billing unit and package size should be one each per Section 5.5.1 of the NCPDP Billing Unit Standard Implementation Guide because of the two different billing units for two different clinical components.

The drug data compendia currently have the package size as two on their files. Due to historical records and potential audit issues, a practice of selecting a date for a coordinated change is followed. There was agreement on the task group call to make the change on October 1. Four of the six compendia have confirmed they can make the change on the selected date. However, the remaining two drug data compendium companies are unable to meet the October 1st date due to internal limitations. One can accommodate the October 1st date for the majority of their clients receiving files daily or weekly but not for clients with monthly files as their data has already been extracted for October 1st. Monthly clients will have the updated information on November 1st. The other drug data compendium can have their files updated for October 15th.

On September 23, 2020, the task group leadership notified the Centers for Medicare and Medicaid Services (CMS) of the task group's recommendation to change the package size via an email message to Ruth Blatt, Health Insurance Specialist, CMS.

The enclosed QUIC form has been updated with discussion notes and the task group's recommendation. During Work Group 2's session for NCPDP's Interim Joint Technical Work Group Meetings, the recommendation will be voted on by the Work Group membership. Following work group approval, the QUIC form resolution will be posted to the NCPDP website.

For direct inquiries or questions related to this letter, please contact:

Terry Fortin
Assistant Senior Manager, Standards Development
NCPDP
E: standards@ncdp.org

Sincerely,



Lee Ann Stember
President & CEO
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Enclosure: QF 202005 JELMYTO_20200728_20200825_20200922.doc

cc: NCPDP Board of Trustees