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VIA ELECTRONIC MAIL

September 21, 2020

Ms. Terry Fortin
Assistant Senior Manager, Standards Development
National Council for Prescription Drug Programs, Inc.
9240 East Raintree Drive
Scottsdale, AZ 85260
E-Mail: tfortin@ncpdp.org

Re: QUIC Form 202005 JELMYTO™ (mitomycin) Carton for Reconstitution (UroGen Pharma, Inc.)

Dear Ms. Fortin:

On behalf of our client, UroGen Pharma, Inc., we are writing with regard to the WG2 Product Review and Billing Unit Exception Task Group review of JELMYTO™. UroGen greatly appreciates the Task Group's August 25, 2020 decision to treat JELMYTO™ as a kit and revise the assigned carton Package Size to "1" for JELMYTO™ (NDC 72493-0103-03), with an effective date of October 1, 2020. The only unresolved question for the Task Group was the appropriate manner in which this would be achieved in light of the Task Group's approach to other products not having JELMYTO™'s unique product profile.

We are writing to convey the urgency with which we hope that this remaining issue may be resolved for the benefit of patients, providers and payers. As you have already determined, the current assignment of 80 billable units to JELMYTO™ exceeds the maximum volume of JELMYTO™ that may be administered to a patient per instillation (i.e., 15 mL, which is 60 billable units) and is inconsistent with the product's FDA-approved label. This has resulted in significant confusion in the marketplace, with numerous payers repeatedly overpaying for the product, and in certain cases, delaying patient access to treatment in order to address the coding and billing inconsistencies presented by the current situation.

We appreciate the careful consideration that the Task Group takes in making its recommendations, and the concern for how a decision related to JELMYTO™ could be viewed

by others in the future. The active ingredients, preparation, dosing and administration of JELMYTO™ are unique, however, and should be reflected accurately in the product's coding and billing assignments. Thus, as our client has previously advised you, we believe that adoption of a correction/exception to NCPDP's standard assignments would be an acceptable approach given the unique circumstances presented by JELMYTO™. We respectfully urge the Task Group to implement the correction/exception no later than October 1, 2020, when a unique HCPCS code (C9064) for JELMYTO™ will become effective. If this issue is not resolved by that time, the coding and billing for JELMYTO™ will be further complicated, resulting in additional consequences to patients, providers and payers that will require more intensive efforts to address.

Please do not hesitate to contact us if we can provide additional information or be of assistance to the Work Group on this matter. We would also welcome your sharing this letter with the Work Group prior to the Task Group's scheduled September 22, 2020 meeting on this issue.

Thank you for your consideration.

Sincerely,

Preeya Noronha Pinto
David J. Farber

cc: Stephen Barbera, BSN, RN
Vice President, Market Access
UroGen Pharma, Inc.