November 1, 2018

Sally Seymour M.D.
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary, Allergy, and Rheumatology Products
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

References: Enbrel® (etanercept) BL 103795 Sequence 0623
Request for advice on PFS strength labeling

Attention: LCDR Andrew Shiber, PharmD, Office of Biotechnology Products

Dear Drs. Seymour and Shiber,

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization consisting of more than 1,400 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system. Through a consensus building process in collaboration with other industry organizations, our members develop these solutions to improve safety, privacy and healthcare outcomes for patients and healthcare consumers, while reducing costs in the system.

It is our understanding the FDA has requested Amgen to change the description of strength to remove the fill volumes of 0.98mL (50mg PFS) and 0.51mL (25mg PFS) from the label and change to 1mL and 0.50mL, respectively. NCPDP respects the FDA's role in ensuring patient safety; however, this change will result in major disruption within the marketplace affecting various stakeholders and potentially patient safety. Changing the strength and/or fill volume of a product that has been available for more than 20 years could cause:

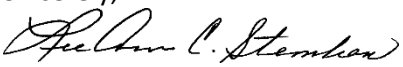
- Healthcare provider and patient confusion regarding correct volume, as both products with differing volumetric designations will exist in the marketplace at the same time; leading to patient adherence and safety issues
- Rejected claims due to fill volume discrepancies across payers and pharmacies
- Restatement of historical package fill volume for appropriate payment
- Audit justifications on payment changes and inventory tracking

For these reasons, NCPDP respectfully requests the FDA work with Amgen on allowing the use of the former label fill volume as this approach will lessen the risk to patient safety and impact to the market. If this is not an option, NCPDP strongly recommends the FDA consider the assignment of new NDCs correlating to new fill volumes and allow for ample time needed for healthcare system updates and dissemination of information to stakeholders.

If needed, NCPDP is available to discuss further.

For direct inquiries or questions related to this letter, please contact:
Elise Balden, Standards Development
National Council for Prescription Drug Programs
Email: ebalden@ncpdp.org

Sincerely,



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