



January 2014

Commander Krista Pedley, Director  
Office of Pharmacy Affairs ("OPA")  
Health Resources and Services Administration ("HRSA")  
Department of Health and Human Services ("HHS")  
5600 Fishers Lane, Parklawn Building, Mail Stop 10C-03  
Rockville, Maryland 20857

**Re: Limited Distribution System for Betaseron®**

Dear Commander Pedley:

Bayer HealthCare Pharmaceuticals Inc. ("Bayer") distributes Betaseron® (interferon beta-1b) 0.3 mg (National Drug Code ("NDC"): 50419-524-35 and 50419-523-35) ("Betaseron"), a subcutaneously injected lyophilized protein product used for the treatment of relapsing forms of multiple sclerosis ("MS").

Beginning with the first quarter of 2014 ("2014Q1"), we anticipate that we will be unable to meet the demand for Betaseron. The risks imposed by anticipated unpredictability in demand are heightened by the critical role this drug plays in the lives of many patients with relapsing forms of MS. In an effort to ensure that all of our customers have an equal opportunity to access Betaseron, beginning in 2014Q1, we are instituting a limited distribution system. We anticipate that this limited distribution system will remain in place for the foreseeable future and will best ensure that all patients of all providers have equal access to Betaseron.

The limited distribution system will impact all customers in a fair and consistent fashion. As detailed below, based on our review of the guidance received from OPA, this system complies with the relevant 340B program guidance. Please feel free to share this information with 340B covered entities and other interested parties as you think appropriate.

**Limited Distribution System**

Beginning with all Betaseron orders received on or after January 1, 2014, Bayer will implement a limited distribution system, which will limit the number of Betaseron units available to each United States customer. The amount of the product available to each customer will be limited to that customer's average quarterly purchase volume in the third quarter of 2013 (*i.e.*, between July 1, 2013 and September 30, 2013) ("the base period") determined on a percentage basis and then applied to the current quarter's available supply. For new direct customers with no purchases of Betaseron during the base period, Bayer has established an

allocation percentage for new customers by selecting another similarly situated direct customer's allocation percentage and applying that percentage to the current quarter's Betaseron supply amount.

Under this limited distribution system, customers' orders for Betaseron will be filled on a first-in, first-out ("FIFO") basis, until a customer reaches its predetermined limit for the quarter. A customer that reaches its quarterly limit may place additional orders for Betaseron at the beginning of the subsequent quarter (subject, of course, to that subsequent quarter's limit). Bayer will not require minimum purchase amounts per transaction, and importantly, a customer's 340B participation status and the price a customer pays for Betaseron will not affect its quarterly allotment.

Customers may continue to order Betaseron through their normal distribution pathway (either direct from Bayer or through a wholesaler or distributor) under the limited distribution system. We will advise wholesalers of their purchasing limits and will ask wholesalers to accordingly limit Betaseron sales to all of their customers using the same methodology, base period, and other requirements that Bayer is employing with respect to its direct customers. Should some of Bayer's customers choose not to purchase their full allocation of Betaseron, five business days before the end of the quarter, Bayer will offer the excess for sale to all customers on a FIFO basis.

## **Conclusion**

Based on our past experience and current supply forecasts, Bayer anticipates that, in the absence of an limited distribution system, Bayer will be unable to meet demand, which threatens to affect the ability of hundreds of thousands of individuals with relapsing MS to obtain Betaseron from their customary healthcare provider. Without equitable and non-discriminatory restrictions on Betaseron purchasing beginning in 2014Q1, 340B covered entities, as well as the Medicaid program, the Department of Veteran Affairs and Federal Supply Schedule entities could be precluded from being able to purchase Betaseron. We are implementing this limited distribution system in order to best ensure that all patients of all providers have equal access to Betaseron.

Sincerely,

Bayer HealthCare Pharmaceuticals Inc.