Prescription Status of edaravone and Personal Importation

Health Canada Authorization of edaravone

Patients with Amyotrophic Lateral Sclerosis (ALS), their families and their health care providers want continued access to the latest information available on the treatment options available to them.

Health Canada authorized edaravone (brand name Radicava) for the treatment of ALS on October 4, 2018, following a thorough scientific review. The company, Mitsubishi Tanabe Pharma Canada Inc. (MTPC Inc.), requested, and was granted, a priority review of the drug since there were limited treatment options available for patients living with ALS. Following the priority review, the Notice of Compliance was issued for Radicava, meaning it could be legally sold in Canada.

Prescription Status of edaravone in Canada

MTPC Inc. began marketing Radicava in Canada in November 2019. Since safe use of edaravone requires supervision by a health care practitioner, the drug was it will be added to the PDL to protect the health and safety of Canadians.

The intent of the PDL is to inform health care providers and the public on when a substance requires a prescription to be sold in Canada. In addition, listing a drug on the PDL may facilitate discussions on health care coverage by publicly or privately funded insurance programs. The PDL also serves to provide a quick reference for Health Canada and the Canada Border Services Agency (CBSA) to verify a product's classification and take applicable regulatory action at the border. With the addition to the PDL and subsequent market availability, health care providers are able to begin prescribing Radicava as of November 5, 2019.

Special Access Program Transition

Since May 7, 2018, MTPC Inc. has been making Radicava available to a limited number of patients through a program administered by the manufacturer and authorized by Health Canada's Special Access Program (SAP). MTPC Inc. has informed health care providers that the distribution of Radicava to new patients under this program ceased on October 8, and that patients currently accessing the drug through SAP will be transitioned to the company's patient support program as of November 5, 2019 with no interruption in supply.

Personal Importation of edaravone

In order to not interrupt supply of needed medication during the transition of edaravone to the Canadian market, personal importation of edaravone will continue to be permitted until October 1, 2020, by mail/courier or on the individual's person.

In all cases of personal importation, the drug must be shipped/carried in appropriate packaging (i.e., hospital or pharmacy dispensed packaging, retail packaging, or with the original label). In addition, supporting documentation from the patient's physician must accompany the package and clearly

indicate that the drug is for the individual's own personal use or for someone whom they are responsible for and travelling with. The quantity for import must not exceed a 90-day supply or a single course of treatment based on the directions for use, whichever is less.

Patients and their families that have been importing edaravone into Canada for personal use should speak with their health care provider about continued access.

Health Canada will continue to monitor the situation leading up to October 1, 2020, to determine whether access via personal importation is still required.

Health Canada remains committed to working with the company, patients and health care providers to help patients access the medications they need.

If you require further information on the personal importation policy, please contact hc.hpbcp-pcpsf.sc@canada.ca.