NHMHP-IDSP0RD-5/1/2021-IDSP-NATIONAL HEALTH MISSION-HP

आज़ादी का अमृत महोत्सव

रोली सिंह, भा.प्र.से.
Roli Singh, I.A.S.
अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)
Additional Secretary & Mission Director (NHM)

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110011

D.O. No. 11037/91/2021-Grants (RD)
Dated: 21st April 2023

Dear Colleague,

The National Policy for Rare Diseases (NPRD-2021) has been notified in March 2021, and the policy document can be accessed at https://main.mohfw.gov.in/documents/policy. The policy aims at lowering the incidence and prevalence of Rare Diseases based on an integrated and comprehensive preventive strategy encompassing awareness generation, screening and counseling programme. In terms of Para 6.2 of the policy, the Rare Diseases are categorized under 3 groups by experts based on their clinical experience and treatment availability.

The Department of Revenue, Ministry of Finance, vide their Notification No. 02/2022-Customs dated 01.02.2022 had given exemption from payment of Basic Customs Duty for drugs or medicines used in the treatment of Rare Diseases when imported by Centres of Excellence (CoEs), specified in NPRD, 2021, or any person or institution, on recommendation of any Centre of Excellence listed in NPRD, 2021, certifying that the person (by name) for whom the drugs or medicines are imported, is suffering from a Rare Disease (to be specified by name) and requires the drugs or medicines for the treatment of the same.

In continuation of the above mentioned Notification, Department of Revenue, Ministry of Finance, vide Notification No. 17/2023-Customs dated 29th March, 2023 (copy enclosed), has now *provided full exemption from payment of Basic Customs Duty (BCD) on all Drugs, Medicines or Food for Special Medical Purposes (FSMP), specified in 'List 38', imported for personal use for treatment of rare diseases identified and categorized under National Policy for Rare Diseases (NPRD), 2021.* This exemption will result in substantial cost savings, and provide much needed relief to the patients.

In order to avail this exemption, the individual importer has to produce a Certificate of Recommendation for exemption from the payment of customs duty in the "Form for Drugs/Medicines/FSMP used for the treatment of Rare Diseases covered under List 38 of the Notification dated 29.03.2023" certified by the Director General or Deputy Director General or Assistant Director General, Health Services, New Delhi; Director of Health Services of the State Governments or the Chief Medical Officer/Civil Surgeons of the Districts.

I would request you to give adequate publicity about the provisions contained in the above mentioned Notifications, upload the same on appropriate websites of the States/UTs, besides displaying prominently on the Notice Board of Hospitals/Institutes to enable the patients and their kin to benefit from the latest notification.

with regards,

Yours sincerely,

(Roli Singh)

Encl: As above

Principal Secretary Health (all States/UTs)

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	Certificate No..... of ..... (year) Certified that the medicine.....(name of the Drug/Medicine/FSMP) to be used for the treatment of .....(patient name), is a Drug/Medicine/ Food for Special Medical Purposes (FSMP) used specifically for treatment of rare disease specified in List 38 and exemption from the payment of customs duty is recommended. Signature with date of Director General / Deputy Director General / Assistant Director General, Health Services, New Delhi or Director of Health Services or District Medical Officer/Civil Surgeon. and (c) the importer produces the said certificate to the Deputy Commissioner of Customs or the Assistant Commissioner of Customs, as the case may be, at the time of clearance, or gives an undertaking as acceptable to the Deputy Commissioner or the Assistant Commissioner to furnish the said certificate within such period as may be specified by the Deputy Commissioner or the Assistant Commissioner, failing which to pay duty leviable thereon.

III. (1) in List 4, after item number 111 and the entries relating thereto, the following entry shall be inserted, namely: -

"(112) Pembrolizumab (Keytruda)";

(2) after List 37 and the entries relating thereto, the following list and entries shall be inserted, namely: -

"List 38 (See S. No. 607B of the Table)

1. Lysosomal Storage Disorders (LSDs)
2. Adrenoleukodystrophy
3. Severe Combined Immunodeficiency (SCID)
4. Chronic Granulomatous disease
5. Wiskot Aldrich Syndrome
6. Osteopetrosis
7. Fanconi Anemia
8. Laron's Syndrome
9. Tyrosinemia
10. Glycogen storage disorders (GSD) I, III and IV due to poor metabolic control, multiple liver adenomas, or high risk for

Hepatocellular carcinoma, or condition of substantial cirrhosis, liver dysfunction, or progressive liver failure
11. Maple Syrup Urine Disease (MSUD)
12. Urea cycle disorders
13. Organic acidemias
14. Autosomal recessive Polycystic Kidney Disease
15. Autosomal dominant Polycystic Kidney Disease
16. Phenylketonuria (PKU)
17. Non-PKU hyperphenylalaninemia conditions
18. Homocystinuria
19. Urea Cycle Enzyme defects
20. Glutaric Aciduria type 1 and 2
21. Methyl Malonic Acidemia
22. Propionic Acidemia
23. Isovaleric Acidemia
24. Leucine sensitive hypoglycemia
25. Galactosemia
26. Glucose galactose malabsorbtion
27. Severe Food protein allergy
28. GH deficiency
29. Prader Willi Syndrome
30. Turner syndrome
31. Noonan syndrome
32. Acidemias, mitochondrial disorders
33. Acute Intermittent Porphyria
34. Wilson's Disease
35. Congenital Adrenal Hyperplasia
36. Neonatal onset Multisystem inflammatory Disease (NoMID)
37. Gaucher Disease Type I and III
38. Hurler Syndrome [Mucopolysaccharisosis (MPS) Type I]
39. Hunter syndrome (MPS II)
40. Pompe Disease
41. Fabry Disease
42. MPS IVA
43. MPS VI
44. Cystic Fibrosis.
45. Duchenne Muscular Dystrophy
46. Spinal Muscular Atrophy
47. Wolman Disease
48. Hypophosphatasia
49. Neuronal ceroid lipofuschinosis
50. Hypophosphatic Rickets
51. Atypical Hemolytic Uremic Syndrome".