

The Health Service (Benefit) (Limited List) (Pharmaceutical Benefit) (Amendment No. 5) Regulations, 2021

<i>Made</i>	<i>8th September, 2021</i>
<i>Coming into operation</i>	<i>9th September, 2021</i>
<i>Laid before the States</i>	<i>, 2021</i>

THE COMMITTEE FOR HEALTH & SOCIAL CARE, in exercise of the powers conferred on it by sections 10 and 35 of the Health Service (Benefit) (Guernsey) Law, 1990^a and section 1 of the Health Service (Benefit) (Limited Lists) Ordinance, 2004^b, and all other powers enabling it in that behalf, hereby makes the following Regulations:-

Amendment to the 2004 Regulations.

1. In the Schedule to the Health Service (Benefit) (Limited List) (Pharmaceutical Benefit) Regulations, 2004^c ("the 2004 Regulations") -

^a Ordres en Conseil Vol. XXXII, p. 192; amended by Order in Council No. IX of 2003; No. II of 2011; No. IV of 2018; Recueil d'Ordonnances Tome XXVI, pp. 177 and 483; Ordinance Nos. XXII and XXVII of 2002; Nos. XXI and XXXIII of 2003; No. XLII of 2006; No. XLIII of 2007; No. XXII of 2015; Nos. IX and XLIV of 2016; and No. XVI of 2020.

^b Ordinance No. XIII of 2004; amended by Ordinance No. XXXIV of 2013 and No. XXV of 2017.

^c G.S.I. No. 9 of 2004; amended by G.S.I. No. 42 of 2004; Nos 18, 25 and 38 of 2005; Nos 12, 18, 26, 36 and 46 of 2006; Nos 3, 5, 6, 16, 17 and 32 of 2007; Nos 11, 23, 29, 31, 47, 50 and 76 of 2008; Nos 16, 35, 43, 47 and 56 of 2009; Nos 5, 32, 48, 88, 91 and 99 of 2010; Nos 5, 13, 19, 37, 38 and 52 of 2011; Nos 5, 25, 33 and 52 of 2012; Nos 5, 27, 35, 42, 68, 78 and 87 of 2013; Nos 8, 11, 16, 25, 57, 69 and 99 of 2014; Nos 9, 33 and 106 of 2015; Nos 10, 17, 25, 31 and 49 of 2016; Nos 48, 69, 78, 88 and 117 of 2017; Nos 6, 9, 16, 28, 35, 40 and 43 of 2018; Nos 1, 68, 77, 82, 91, 106 and 114 of 2019 and Nos. 3, 55, 93 and 144 of 2020 and Nos 16, 35, 60 and 65 of 2021.

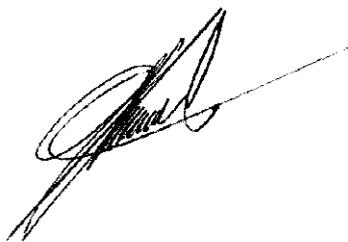
- (a) insert the entries set out in Schedule 1 to these Regulations in the appropriate places and under the appropriate headings, and
- (b) for each pharmaceutical benefit in column 3 of Schedule 2 to these Regulations listed in the Schedule to the 2004 Regulations (under the reference and heading in columns 1 and 2 of Schedule 2 to these Regulations respectively), substitute the corresponding pharmaceutical benefit in column 4 of Schedule 2 to these Regulations, and
- (c) delete the entries set out in Schedule 3.

Citation, commencement and extent.

2. (1) These Regulations may be cited as the Health Service (Benefit) (Limited List) (Pharmaceutical Benefit) (Amendment No. 5) Regulations, 2021, and shall come into force on the 9th day of September, 2021.

(2) These Regulations shall have effect in the Islands of Guernsey, Alderney, Herm and Jethou.

Dated this 8th day of September, 2021.



A. H. BROUARD

President of the States Committee for Health & Social Care

For and on behalf of the Committee

SCHEDULE 1

Regulation 1(a)

ENTRIES TO BE INSERTED IN THE SCHEDULE TO THE 2004 REGULATIONS

British National Formulary (BNF) Section	Heading	Pharmaceutical Benefit
3.2.1	Kallikrein Inhibitors	Lanadelumab, solution for injection vial, and solution for injection in pre-filled syringe, 300mg. (In accordance with NICE TA number 606 or any revision thereof only). Initiated under specialist supervision.
3.5	Antifibrotics	Pirfenidone, Film-coated Tablets, 267mg, 534mg and 801mg. Hard Capsules 267 mg. (In accordance with NICE TA number 504 or any revision thereof only). Initiated under specialist supervision.
4.4.6	Analgesics > Opioids	Oxycodone, Tablet M/R 15mg.
4.6.1a	Calcitonin Gene-Related Peptide Inhibitors	Erenumab, solution for injection in pre-filled syringe and prefilled pens, 70mg and 140mg. (In accordance with NICE TA number 682 or any revision thereof only). Initiated by a specialist.
4.6.1a	Calcitonin Gene-Related Peptide Inhibitors	Galcanezumab, solution for injection in pre-filled pen 120mg/1ml. (In accordance with NICE TA number 659 or any revision thereof only). Initiated by specialist.
5.6.3b	Nucleotide Analogues	Sofosbuvir–velpatasvir, film coated tablets, 400mg/100mg and 200mg/50mg. (In accordance with NICE TA number 430 or any revision thereof only). Initiated by a specialist /PEH pharmacy dispensing only.
8.1.1	Monoclonal Antibodies/Anti-Lymphocyte	Ofatumumab, solution for injection in pre-filled pen, 20mg. (In accordance with NICE TA number 699 or any revision thereof only). Treatment should be initiated by a physician experienced in the management of neurological conditions.

British National Formulary (BNF) Section	Heading	Pharmaceutical Benefit
8.8.7	Antineoplastic Drugs/Protein Kinase Inhibitors	Abemaciclib, Film-coated tablets, 50 mg, 100mg, 150mg. (In accordance with NICE TA number 563 or any revision thereof only). Initiated by a specialist.
8.8.7	Antineoplastic Drugs/Protein Kinase Inhibitors	Alectinib, hard capsules, 150mg (In accordance with NICE TA number 536 or any revision thereof only). Specialist use only.
8.8.7	Antineoplastic Drugs/Protein Kinase Inhibitors	Binimetinib, film-coated tablets 15mg (In accordance with NICE TA number 562 or any revision thereof only). In combination with Encorafenib, specialist use only.
8.8.7	Antineoplastic Drugs/Protein Kinase Inhibitors	Cabozantinib, film-coated tablets 20mg, 40mg, 60mg. Hard capsules 20mg, 80mg. (In accordance with NICE TA number 516 or any revision thereof only). Initiated by a specialist.
8.8.7	Antineoplastic Drugs/Protein Kinase Inhibitors	Cabozantinib film-coated tablets 20mg, 40mg, 60mg. Hard capsules 20mg, 80mg. (In accordance with NICE TA number 542 or any revision thereof only). Initiated by a specialist.
8.8.7	Antineoplastic Drugs/Protein Kinase Inhibitors	Encorafenib, hard capsules 50mg and 75mg. (In accordance with NICE TA number 562 or any revision thereof only). In combination with Binimetinib, specialist use only.
8.8.7	Antineoplastic Drugs/Protein Kinase Inhibitors	Encorafenib, hard capsules 50mg and 75mg. (In accordance with NICE TA number 668 or any revision thereof only). In combination with cetuximab, specialist use only.
8.8.7	Antineoplastic Drugs/Protein Kinase Inhibitors	Neratinib, Film-coated tablets, 40mg (In accordance with NICE TA number 612 or any revision thereof only). Specialist use only.
8.8.7	Antineoplastic Drugs/Other	Venetoclax, film-coated tablets, 10mg, 50mg, and 100mg.

British National Formulary (BNF) Section	Heading	Pharmaceutical Benefit
		(In accordance with NICE TA number 561 or any revision thereof only). Specialist use only.
11.1.2	Corticosteroids	Hydrocortisone sodium phosphate Eye drops, Unit dose, 3.35mg/ml.
13.3.1	Interleukin Inhibitors	Brodalumab, Solution for Injection in prefilled syringe, 210mg. (In accordance with NICE TA number 511 or any revision thereof only). Under expert supervision. Must be prescribed and dispensed by brand name only.
Part IX A Drug Tariff	Appliances	IrriSedo Balloon System. As per current Drug Tariff. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	IrriSedo Balloon System – Accessory Set Regular. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	IrriSedo Balloon System – Catheter Set Regular. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	IrriSedo Klick Control Unit. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	IrriSedo Klick Starter Catheter Set. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	IrriSedo Mini Set. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	Navina Smart System. As per current Drug Tariff. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	Navina Consumable Set. As per current Drug Tariff. Available for appliance card holders only.

British National Formulary (BNF) Section	Heading	Pharmaceutical Benefit
Part IX A Drug Tariff	Appliances	Peristeen System. All products in current Drug Tariff. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	Peristeen Accessory Unit. All products in current Drug Tariff. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	Peristeen Rectal Catheters. All products in current Drug Tariff. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	SomaCorrect Extra. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	SomaErect Response II. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	SomaErect Response II XL. Available for appliance card holders only.
Part IX A Drug Tariff	Appliances	Ultimate (Surefit) Maintenance Ring Set. Available for appliance card holders only.

SCHEDULE 2

Regulation 1(b)

PHARMACEUTICAL BENEFITS TO BE SUBSTITUTED IN THE SCHEDULE TO
THE 2004 REGULATIONS

Column 1: British National Formulary (BNF) Section	Column 2: Heading	Column 3: Current Pharmaceutical Benefit	Column 4: New Pharmaceutical Benefit
2.4.1c	Endothelin Receptor Antagonists	Macitentan, Tablet 10mg Royal Brompton Hospital prescribing only	Macitentan, Tablet 10mg. Tertiary Centre prescribing and dispensing only.
4.4.1	Neurotoxins (Botulinum Toxin)	Botulinum A Neurotoxin Comp_Inj 100iu VI for specialist use only	Botulinum A Neurotoxin Comp Injection 50iu, 100iu, 200iu, Vial. For specialist use only.

SCHEDULE 3

Regulation 1(c)

PHARMACEUTICAL BENEFITS TO BE DELETED IN THE SCHEDULE TO
THE 2004 REGULATIONS

British National Formulary (BNF) Section	Heading	Pharmaceutical Benefit
Part IX A Drug Tariff (No 3)	Appliances	Libre Sensor: Maximum of two sensors per 28 days.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations add drugs and dressings to the list of products that may be prescribed as pharmaceutical benefit and amend the permissible prescribing of two products already on that list.

These Regulations come into force on the 9th September, 2021.

