Interim sequential biologics policy and process for considering Locally Commissioned PbR-excluded drug requests in line with RMOC advisory statement on "sequential use of biologic medicines"

and which are not covered by existing SWL high cost drug pathways and are not suitable for consideration through IFR process

(Version 3.3)

Introduction

Following review of RMOC advisory statement on "Sequential use of Biologic Medicines (January 2020)" it was concluded that SWL pathways require review by clinical networks and may need to be adjusted to allow more lines of therapy if supported by evidence and clinical input. This particularly applies to the following pathways:

- Crohn's Disease
- Psoriasis
- Ulcerative colitis

However, all SWL High Cost Drug pathway updates are delayed due to Covid-19. Patients for whom there is no suitable alternative (i.e. pre-biologic or non-high cost drug treatment) may have a disease flare if treatment options in commissioned SWL high cost drug pathways are exhausted.

This interim policy will bridge the gap, until pathways are updated and approved in line with new information and evidence with input from all required staff. It is subject to regular review as determined by the SWL Integrated Medicines Optimisation Committee. Outcomes of all patients will be monitored through audit of patient response to treatment on Blueteq continuation forms.

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Approved by	**Date**
NHS SWL CCG Chief Pharmacists (or deputy) • Merton borough • Sutton borough • Croydon borough • Kingston and Richmond borough • Wandsworth borough	20/04/2020
SWL Medicines Optimisation Group (virtual)	16/04/2020
SWL Integrated Medicines Optimisation Committee (IMOC)	16/06/2021 18/08/2022
SWL Finance and Advisory Committee (FAC)	19/10/2021
Financial sign off: • Croydon University Hospital: Chief Pharmacist; Director of Finance • Epsom and St. Helier Hospital: Chief Pharmacist, Head of Financial Management • Kingston Hospital: Chief Pharmacist, Director of Finance • St. George's Hospital: Deputy Chief Financial Officer	 22/22/2021 02/12/2021 22/12/2021 10/12/2021

Approved: June 2021 (version 1)

Interim update: October 2022 (version 2), Aug 2023 (version 3) March 2024 (version 3.3)

Review date: Sept 2024 (or earlier if indicated)

Interim Policy

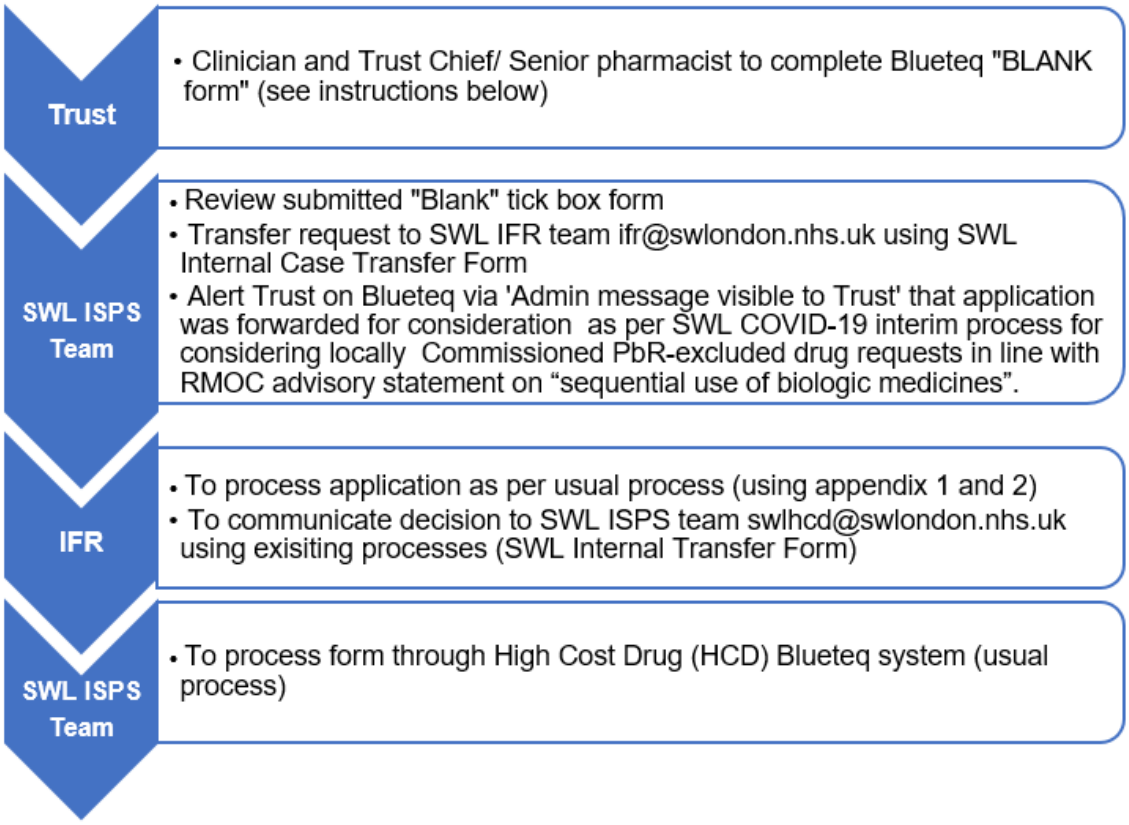
This process only applies:

- where there is no individual clinical exceptional circumstance that would normally be processed through IFR process
- to request **one** additional step to existing SWL pathways if there is a drug with alternative mode of action available which has not yet been used (i.e., outside the SWL High Cost Drug pathway taking into consideration RMOC advisory statement on "Sequential use of Biologic Medicines (January 2020) (see appendix 1)

This process does not apply:

- for patients who have already received drugs outside the standard SWL pathway. These would need to be submitted through IFR process (if appropriate).

Process map



Instructions for completing - Funding application for ICB commissioned Aligned Payment and Incentive (API) (sequential biologic request outside SWL pathway) - BLANK form

All forms must include the following:

- Reasons for request: including extenuating circumstances considering RMOC advisory statement on "Sequential use of Biologic Medicines (January 2020)
- Current treatment and full drug history including pre-biologic, biologic and other high cost drugs or treatments (including dose frequency, duration, measure taken to circumvent side effects, reasons for stopping)
- Baseline and current disease activity scores for each treatment with dates
- Other clinical information (test results etc)
- Specify the brand (if applicable)

Appendix 1: Current commissioned pathway and interim process.

Note: All new NICE TA approved drugs, not listed and awaiting IMOC approval will also be considered as part of this policy

Indication	**Current Commissioned pathway (number of treatment steps)**	**Interim process for additional biologic only for those patients who have not received all modes of action**
Crohn's Disease*	3 steps + 1 switch within anti-TNF class	5 steps + 1 switch within anti-TNF class
Ulcerative colitis*	3 steps + 1 switch within anti-TNF class	6 steps + 1 switch within anti-TNF class
Psoriasis*	3 steps (includes 1 switch within anti-TNF class) + apremilast + dimethyl fumarate + deucravacitinib	4 steps + 1 switch within anti-TNF class + apremilast + dimethyl fumarate + deucravacitinib

*Refer to the sequential IL inhibitor policy

The modes of action for biologics considered will be as follows (last updated 7/11/2023)**:**

Drug class	**Sub-type**	**Drugs within class**
TNF – alpha inhibitor		Adalimumab
		Etanercept
		Certolizumab
		Golimumab
		Infliximab
Interleukin inhibitors (Differentiation between IL-inhibitors is applied where there is more than one sub-type of IL-inhibitor approved as a treatment option i.e., psoriatic arthritis, psoriasis and Crohn's disease. This does not apply to atopic dermatitis (i.e., dupilumab (IL4/13 inhibitor) and tralokinumab (IL13 inhibitor)) as there is no information from NICE at present)	IL-6	Sarilumab
	IL-6	Tocilizumab
	IL-17	Bimekizumab
	IL-17	Brodalumab
	IL-17	Ixekizumab
	IL-17	Secukinumab
	IL- 23	Mirikizumab
	IL-23	Guselkumab
	IL-23	Risankizumab
	IL-23	Tildrakizumab
	IL-12/23	Ustekinumab
Janus kinase (JAK) inhibitor		Baricitinib
		Filgotinib
		Tofacitinib
		Upadacitinib
B-cell inhibitor		Rituximab
T-cell co-stimulation inhibitor		Abatacept
Alpha 4 beta 7 integrin		Vedolizumab
Sphingosine 1-phosphate (S1P) receptor modulator		Ozanimod
		Etrasimod

Appendix 2: IFR triage approval periods for initiating treatment.

Indication	Drug	Sub-type	Initial approval period
Crohn's disease	Adalimumab	TNF – alpha	6 Months
	Infliximab	TNF – alpha	6 Months
	Risankizumab	IL-23	16 Weeks
	Upadacitinib	JAKi	24 Weeks
	Ustekinumab	IL-12/23	6 Months
	Vedolizumab	Alpha 4 beta 7 integrin	6 Months
Ulcerative Colitis	Adalimumab	TNF – alpha	6 Months
	Filgotinib	JAKi	12 Months
	Golimumab	TNF – alpha	6 Months
	Infliximab	TNF – alpha	6 Months
	Mirikizumab	IL-23	24 Weeks
	Ozanimod	S1P receptor modulator	10 Weeks
	Etrasimod	S1P receptor modulator	12 weeks
	Ustekinumab	IL-12/23	6 Months
	Upadacitinib	JAKi	16 Weeks
	Tofacitinib	JAKi	6 Months
	Vedolizumab	Alpha 4 beta 7 integrin	6 Months
Psoriasis	Adalimumab	TNF – alpha	16 Weeks
	Bimekizumab	IL-17	16 Weeks
	Brodalumab	IL-17	12 Weeks
	Certolizumab	TNF – alpha	12 Weeks
	Etanercept	TNF – alpha	12 Weeks
	Guselkumab	IL-23	16 Weeks
	Infliximab	TNF – alpha	10 Weeks
	Ixekizumab	IL-17	12 Weeks
	Risankizumab	IL-23	16 Weeks
	Secukinumab	IL-17	12 Weeks
	Tildrakizumab	IL-23	28 Weeks
	Ustekinumab	IL-12/23	16 Weeks