South East London (SEL) – Omalizumab for Chronic urticaria: Outcomes and Monitoring Framework

Key Performance indicators (KPI) to assign specific monitoring for use of Omalizumab for both Chronic Spontaneous Urticaria and angioedema (CSUA) and Chronic Inducible Urticaria (CIndU) within SEL

KPI	Intervention	Target /Standard	Measure and Frequency	Data Source	Who measures	Frequency of reporting – in any financial year
1.	**Audit of adherence to omalizumab eligibility criteria according to pathway**	98% of patients should be initiated on omalizumab as per criteria outlined in the pathway ***[snapshot audit acceptable]***	a) % of patients receiving omalizumab for CSUA as per eligibility* criteria b) % of patients receiving omalizumab for CIndU as per eligibility* criteria *(In the event of less than 98% adherence, exceptions will be reviewed and cohort in SEL vs Non-SEL reported)* *Reasons for deviations in initiation/use of omalizumab outside of eligibility criteria according to pathway to be outlined.	Trust Database	Trusts	Annual
2a.	**Audit of locally commissioned elements of the pathways**: i) Audit of patients receiving dose optimisation of omalizumab	100% of patients are treated in accordance with dose optimising in appropriate patients as per pathway ***[snapshot audit acceptable e.g. quarterly data]***	a) Number of patients receiving dose optimisation of omalizumab (SEL vs Non-SEL) b) Audit of outcomes and actions post review: % continued and interval prescribed/ stopped/switched	Trust Database	Trusts	Annual (due end of September)

Not to be used for commercial or marketing purposes. Strictly for use within the NHS

2b.	**Audit of locally commissioned elements of the pathways**: i) Audit of patients receiving dose escalation of omalizumab	100% of patients should be reviewed at appropriate time points as outlined in the pathway	a) Number of patients receiving dose escalation 1, 2 or 3 of omalizumab (SEL vs Non-SEL) b) % of patients receiving dose escalation 1, 2 or 3 reviewed at appropriate time points as outlined in the pathway c) Audit of outcomes and actions post review: % continued/stopped/switched			Annual (due end of March)
3.	**To ensure patients on off label dosing schedules for omalizumab have been fully counselled on the benefits versus risk of treatment.**	100% of patients on off label dosing schedules have been counselled on the risks versus benefit of treatment and this is documented in the clinical notes/letter. ***[snapshot audit acceptable]***	(x) The number of patients who have clinic notes/letter detailing discussion with patient regarding benefit versus risk with off label dosing regimen. (y) = number of patients on an off-label dosing schedule for omalizumab [x/y] x 100 = percentage of patients under the care of the service who have been counselled on their off-label treatment.	Trust Database	Trusts	Annual
4.	**Measure impact of the pathway on overall service commissioning costs to ensure value for money**	High Cost drug use of Omalizumab in SEL ICB	Breakdown of omalizumab use and cost by indication at regular intervals (CSUA v CIndU) by Trust, for SEL ICB	Acute activity (Finance reporting	SEL ICB (Business Intelligence) + Trust high cost drug reporting	Review of data at dermatology pathway meetings

Additional Notes:

- Trusts with Epic EPMA systems will have some initial limitations of data extraction and flows. In future, there should be optimisation with Epic data reporting to facilitate the above KPIs and audits.
- Biosimilar implementation will be tracked separately to this monitoring framework.