Category C (Local) GUIDELINE TEMPLATE

Standard Operating Procedure for Steroid Tapering when Managing Immunotherapy Related Toxicities	University Hospitals of Leicester NHS NHS Trust **Trust Reference C47/2024**

1. Introduction and Who Guideline applies to

This guideline refers to the steroid tapering for management of immunotherapy induced adverse effects. It encompasses the pathway of care to follow when a patient over the age of 25 who has received steroids for immunotherapy toxicity in adult services who in turn presents to the University Hospitals of Leicester.

2. Guideline Standards and Procedures

This guideline is for utilisation by all trained medical and nursing staff who will be asked to assess and/or treat patients with Immune Related Adverse Event, (irAE's). Its ambition is to ensure that there is a robust referral process in place. It's purpose is to reduce inpatient stay and minimise patient admissions. This guideline is in reference to the management of irAEs with steroids. Its purpose is to provide clinical staff with steroid tapering guidance.

3. Management plan for patients discharged home on Steroid Tapering

The referral process to the IO nursing service

Any patient who is an inpatient at UHL, who requires input from the Immunotherapy Nurse led service should be referred using the ICE referral pathway.

For any patient who is being discharged from an inpatient episode but requiring follow up from the immunotherapy nurse led service, it is the responsibility of the discharging medical team to inform the IO nurses; to provide information to the patient including:- IO Nurse contact details; Steroid information leaflet and card.

The Immunotherapy Clinical Nurse Specialist will conduct twice weekly toxicity clinics, to ensure that the patients remain well, and clarify the steroid tapering (weaning) process and subsequent appointments.

Please refer to appendix 1 – adapted from the Clatterbridge Cancer Centre – Steroid Tapering Pathway

The Immunotherapy Clinical Nurse Specialist will arrange for the patient to have a repeat cortisol level taken 5-7 days post completion of the steroid tapering process. This test

needs to be taken at 09:00 of the identified date. If these are within normal parameters, the patient will be referred back to their treating consultant to arrange a further treatment plan. If the cortisol level is outside of normal parameters; the patient will be referred to the Endocrine Specialist team and appropriate management plan arranged.

This is in alignment with the ESMO clinical guidelines.

Upon successful completion of the Steroid Tapering process, the patient will be referred back to be reviewed by their primary treating consultant.The Immunotherapy Clinical Nurse Specialist will ensure appropriate follow up appointments are provided to the patient.

In the event that the patient is not responding effectively to steroids, the IO Nurse will fully triage the patient. Following this assessment, the decision will be reached as to whether the patient continues on current steroid dosage or to increase the dosage by 10mg. Upon completion of this review, the IO nurse will discuss with the primary treating team or Immunotherapy Consultant Lead or on call team dependent on severity of toxicity. If the treatment plan is approved, the patient will be reviewed by IO nurses the following week. If treatment plan not approved, the patient will receive a follow up call from the IO nurses and advised appropriately.

In the event that toxicity symptoms do not resolve, patients will be referred back to be reviewed by their primary treating consultant and The Immunotherapy Clinical Nurse Specialist will ensure a timely follow up appointments are provided to the patient and liase with the consultant team.

A letter will be sent to the patient's GP, advising that the patient has been receiving treatment for an immunotherapy related toxicity, outlining the management plan with appropriate contact details, should the GP require additional advice.

If the patient has been treated as an inpatient, it will be a requirement that the GP receives a discharge letter.

If the patient has been reviewed in an outpatients clinic, it will be necessary for the GP ro receive a dictated letter either from the oncologist or the IO CNS.

4. Documentation

The Immunotherapy Nurse Specialists will ensure that any patient contacted as part of the toxicity management clinic will be appropriately coded as per identified clinic code.

Annotation of Immunotherapy toxicity and management plan overview will be added to Somerset Cancer Register (SCR).

All outpatients contacts – telephone calls will be recorded on Somerset Cancer Register (SCR) which will provide an up dated management plan which will be visible to all members of the Immunotherapy team, to ensure that a cohesive and consistent plan can be actioned.

All inpatient reviews and management plans will be recorded within the medical notes held on the ward and also on Nerve Centre.

5. Education and Training

Staff Education

Educational updates will be provided for medical and nursing staff by the Immunotherapy CNS and other relevant partnerships.

Relevant staff to be included in an education programme:

- Medical staff within the Emergency Department; Osborne Assessment Unit and both medical and surgical assessment units
- Junior Doctors as part of their clinical rotation induction programme
- Education will also be provided by the Immunotherapy team to practitioners within Primary Care.

Patient Education

Patient education leaflets will be developed and, once approved will be available on 'Your Health' on the UHL intranet website – which will include the leaflet titled **'Steroids: For the Treatment of Immunotherapy Adverse Effects'.**

The Immunotherapy Clinical Nurse Specialist and/or SACT trained nurses will conduct a new case patient talk, providing relevant information regarding immunotherapy and potential side effects/complications; information regarding the 24 hour Emergency help line and contact details for the immunotherapy clinical nurse specialists.

6. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Referrals into the service will be monitored to ensure appropriate and that complete information is received	Audit	IO CNS	3 monthly	Oncology Management Meeting CHUGGS SACT Monthly meeting
Audit will be conducted to ensure there is no doubling up of appointments for steroid weaning, and that timely appointments for returning back to primary consultant are received	Audit	IO CNS	3 monthly	Oncology Management Meeting

7. Supporting References

ESMO https.//www.esmo.org/guidelines

The Clatterbridge Cancer Centre NHS Foundation Trust;

8. Key Words

Immunotherapy; steroids

CONTACT AND REVIEW DETAILS	
Guideline Lead Clair Burroughs – Macmillan Lead SACT Nurse; Dr Meera Chuahan – Medical Consultant in Oncology	**Executive Lead**
Details of Changes made during review: - New document	

Appendix 1- Adapted from The Clatterbridge Cancer Centre NHS Foundation Trust

Oral steroid tapering

- Initiate corticosteroid taper over 3-6 weeks

Tapering Guidance

- Monitor patient by telephone consultation a minimum twice weekly during taper process
- Reduce Prednisolone dose by 10mg every 3/7 (as toxicity allows) until dose is 10mg/day
- Once steroid dose is 10mg/day, further reduce by 5mg for 5 days then discontinue
- If clinicians wish to adjust the steroid tapering process in accordance with their clinical judgement, please ensure this is clearly communicated with the Immunotherapy Clinical Nurse Specialists

Escalation

- If a patients symptoms do not resolve or recur when dose is reduced, refer back to oncology team to advise on management plan.
- If unwell when reviewed in clinic, they will be referred to OAU in the first instance for admission for IV steroid +/- immune suppressant therapy

Intravenous Steroid Tapering

- Corticosteroid taper over at least 3-6 weeks

Tapering Guidance

- Continue IV Methylprednisolone 2mg/kg/day for a total of 5 days then switch to **oral** prednisolone of 1mg/kg/day
- If following a re-flare and re introduction of IV steroids, reduce to 1mg/kg/day of oral prednisolone for 3 days then commence steroid taper

Upon discharge home

- Monitor patient by telephone consultation a minimum twice weekly during taper process
- Reduce Prednisolone dose by 10mg every 3/7 (as toxicity allows) until dose is 10mg/day
- Once steroid dose is 10mg/day, further reduce by 5mg for 5 days then discontinue

ALL PATIENTS SHOULD HAVE A CORTISOL SAMPLE AT 09:00 WITHIN THE 5-7 DAYS FOLLOWING THE COMPLETION OF THEIR STEROID TAPER

If the patient does not respond to steroid management – discuss with the treating clinician and refer to: **Infliximab and Biosimilar Prescribing and Administration for Day Case Adult Patients – UHL Guideline (This is not currently licensed for treatment of Immunotherapy Related AE's)**

Supportive measures:

Hyperglycaemia

A baseline HbA1c should be requested prior to initiation of steroids and random blood sugar monitoring should be undertaken throughout the duration of the steroid treatment. If a new hyperglycaemia is identified, it is necessary that advice is sought fro the Endocrinology team – it may be that the patient will require short term insulin administration. Pre-existing diabetes may require immediate escalation in oral hypoglycaemic agents or insulin

Insomnia

Insomnia is a common side effect of steroids which can be distressing for the patients. Informing the patient of this side effect as well as sleep counselling is important. Patients may require short term prescriptions of sleeping tablets, which should be prescribed as clinically appropriate.

Osteoporosis

Ensure that baseline Vitamin D and Calcium levels are taken when steroids are commenced, and if low, to be replaced as clinically appropriate. Please follow the Leicestershire Guidelines for Osteoporosis https://www.areaprescribingcommitteeleicesterleicestershirerutland.nhs.uk/wp-content/uploads/2015/05/Final-Osteoporosis-guidelines.pdf

Infection

Patients who are receiving the dose equivalent of 25mg of Prednisolone for >6 weeks, PCP Prophylaxis should be considered, with one option being Co-Trimoxazole 80/400mg administered 3 times weekly – Mon/Weds and Fri.

If there are any visual signs of candida, it may be necessary to consider Nystatin oral drops or oral Fluconazole