GUIDELINE FOR THE MANAGEMENT OF IMMUNE-RELATED ADVERSE REACTIONS FOLLOWING IMMUNOTHERAPY TREATMENT

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

This guideline refers to the management of immunotherapy induced adverse reactions. It encompasses the pathway of care to follow, when a patient over the age of 16 who has received immunotherapy in adult services, presents to Worcestershire Acute Hospitals NHS Trust.

This policy refers to patients who may present to the trust via Accident & Emergency who are receiving Immunotherapy elsewhere but who live locally.

This guideline is for use by the following staff groups:

This guideline is for utilisation by trained medical and nursing staff. Educational updates will be provided for medical and nursing staff.

Lead Personnel (s)

Dr. Lisa Capaldi	Clinical lead
Dr N Murukesh	Consultant Medical Oncologist
Mrs Helen Grist	Immunotherapy Clinical Nurse Specialist
Mrs S Cook	Lead Pharmacist
Mrs A Jones	Acute Oncology Nurse Practitioner

Guideline approved by:

Haematology & Palliative Care Governance meeting 10th September 2020

Oncology Governance meeting 15th July 2020

Medicines Safety Committee 14th October 2020

Review Date 13th September 2024

This is the most current document and is to be used until a revised version is available:

Key Amendments made to this document:

Date	Amendment	By
	Guideline approved by Clinical Effectiveness Committee	
9th October 2019	09/10/2019- Document extended for 6 months whilst document is taken through consultants meeting and reviewed	Helen Grist/Lisa Rowberry
May 2020	Document extended for 6 months during COVID-19	
October 2020	Guideline updated and derived from the Clatterbridge ones.	Helen Grist/MSC
20th December 2021	Pneumonitis Guideline added	Helen Grist
13th March 2024	Document extended for 6 months whilst under review.	Helen Grist

Contents

Section:-

Guideline For The Management of Immune-Related Adverse Reactions Following Immunotherapy Treatment

1. INTRODUCTION

This policy refers to the management of immunotherapy induced adverse reactions. It encompasses the pathway of care to follow when a patient over the age of 16 who has received immunotherapy in adult services presents to Worcestershire Acute Hospitals NHS Trust.

2. DEFINITIONS

Immunotherapy agents are a relatively new class of anti-cancer drugs which reactivate the Immune system to destroy cancer cells. The side effect profile for these agents is different from that of standard cytotoxic drugs. They can cause severe immune-related adverse reactions including serious immune-related endocrinopathies, which can be fatal. Thus, it is important to recognise and address symptoms early.

The majority of immune-related reactions occur over the course of treatment. However, they can occur weeks to months after discontinuation of treatment.

3. PRE TREATMENT INVESTIGATIONS AND PATIENT EDUCATION

Prior to commencing treatment, all patients must be informed of the potential side effects (Risk of adverse reactions) and what action to take should they experience these side effects. All patients must be given drug specific information and an immunotherapy alert card containing contact details for the acute oncology service. Patients should be advised to contact the hospital straight away if they have any of the following symptoms:

- Lung : breathing difficulties or cough
- Bowel: watery or loose stools, mucous or blood in stool, stomach pains or cramps
- Liver: eye or skin yellowing, pain on right side of stomach
- Kidney: changes in volume of urine
- Endocrine: extreme tiredness, weight change, headache, visual disturbances

- Diabetes symptoms: excessive thirst, large volumes of urine, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell
- Skin : itching, rash, blisters, ulcers, peeling skin
- Eye : redness, pain, blurred vision
- Other: severe upper abdominal pain, nausea, vomiting, numbness, uncoordinated movements, paralysis, muscle weakness
- Heart problems: Chest pain, breathlessness, tiredness, leg swelling

Prior to initiation of treatment the following bloods should be taken as a baseline:

- FBC, renal, liver and bone profile, Glucose, Cortisol, TSH, LDH, Clotting factors. If Pituirary dysfunction evident for testosterone & Oestradiol FSH, Testosterone to be added if indicated by Consultant.
- In the case of Nivolumab, a baseline ECG should be considered as it can cause cardiotoxicity.

These bloods should be repeated before each cycle.

If the patient is stable on treatment the frequency of the blood tests may be reduced.

Patients should have a face to face or telephone, doctor or nurse led clinic review prior to each treatment cycle. If the patient is stable on treatment the frequency of reviews could be reduced.

If the patient contacts the acute oncology service during normal working hours or presents at the Emergency department, they should be assessed and managed as detailed in the 'Initial Management of Immune-related Adverse reactions' flow chart below.

If the patient contacts the acute oncology service out of hours, the AOS nurse should complete the Immunotherapy 'Out of Hours Checklist' (Appendix 1) and follow the instructions on the checklist.

4. MANAGEMENT OF IMMUNE-RELATED ADVERSE EVENTS INDUCED BY IMMUNOTHERAPY

INITIAL MANAGEMENT of IMMUNE – RELATED ADVERSE REACTIONS

WORKING HOURS: INFORM THE ACUTE ONCOLOGY TEAM OF ADMISSION.
OUT OF HOURS: INFORM THE CONSULTANT ONCOLOGIST ON CALL

On presentation, if no obvious infectious and / or disease-related aetiologies

DO NOT WAIT, TREAT AS:

Immune –Related Adverse Reaction or Endocrinopathy as outlined below in the flow charts.

Follow link for CTC grading criteria: https://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf

WORKING HOURS: Inform the Acute Oncology Team, for pathway of management of patient from Nurse led clinic, consultant clinic, or pre proceed triage see Appendix 5.

OUT OF HOURS: Inform the Acute Oncology service, if patient requires assessment for admission to be directed to ED to be assessed by medics.

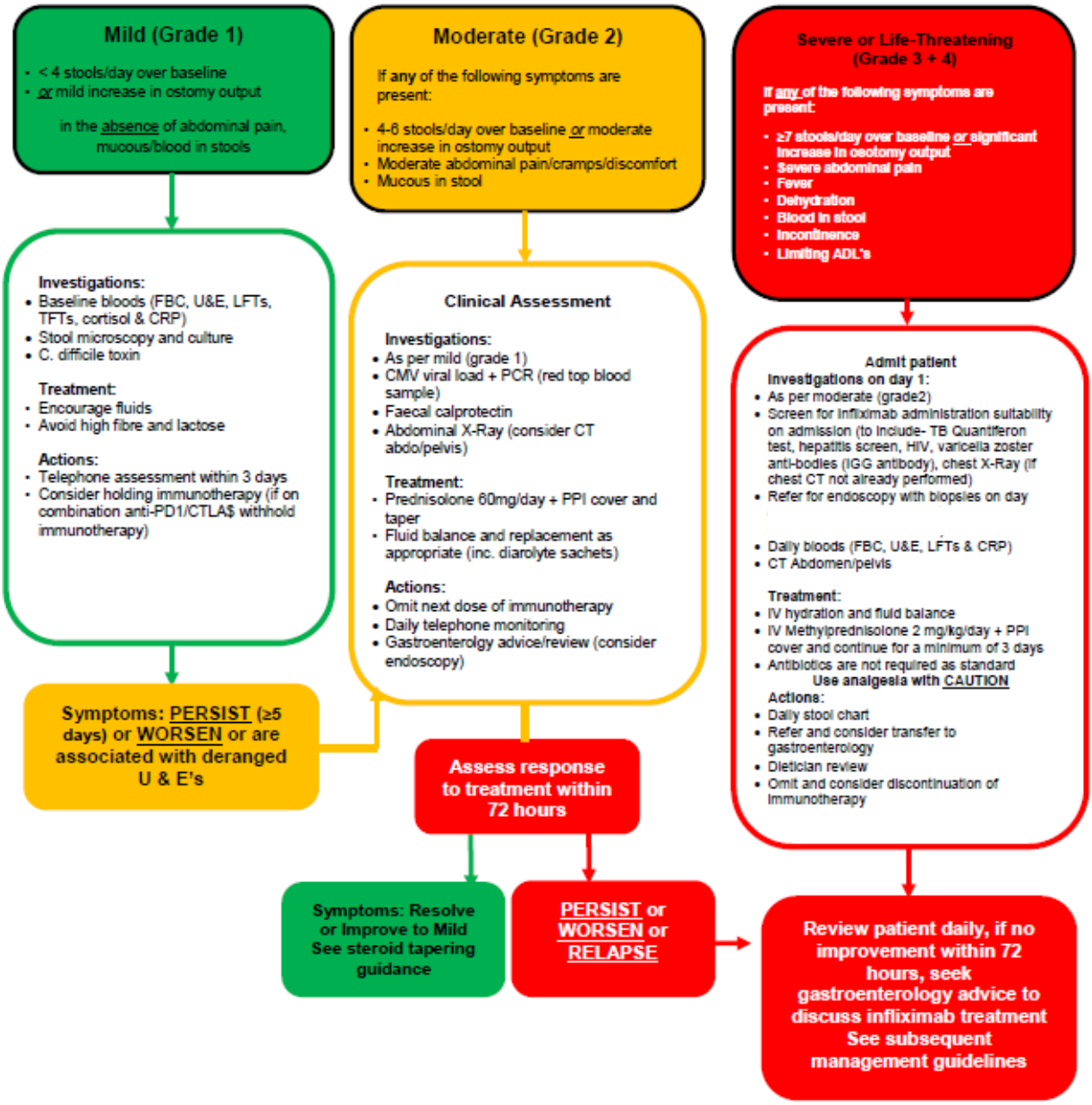
Having assessed the patient as per the guideline in the symptom management for adverse events it may be that referral to a specialist is required. The table below is a list of leads who are able to advise on symptom management as a specialist in their field.

Endocrinology	Dr. Irfan Babar Dr. Munir Babar
Cardiology	Dr. J. Trevelyn
Dermatology	Dr. C.Leitner
Respiratory	Dr. Kate Cusworth
Rheumatology	Dr. Caroline Cardy
Renal	Dr. Martin Ferring
Gastroenterology	Dr. Nic Hudson

Adapted from The Clatterbridge Cancer Centre NHS Foundation Trust Guidelines

Immune-Related Adverse Event: Diarrhoea

Gastrointestinal (GI) irAEs are among the most common and although they are typically mild to moderate in severity, if they are left unrecognised or untreated, they can become life-threatening. These toxicities can be managed effectively in almost all patients by using established guidelines that stress vigilance and the use of corticosteroids and other immunosuppressive agents when necessary.



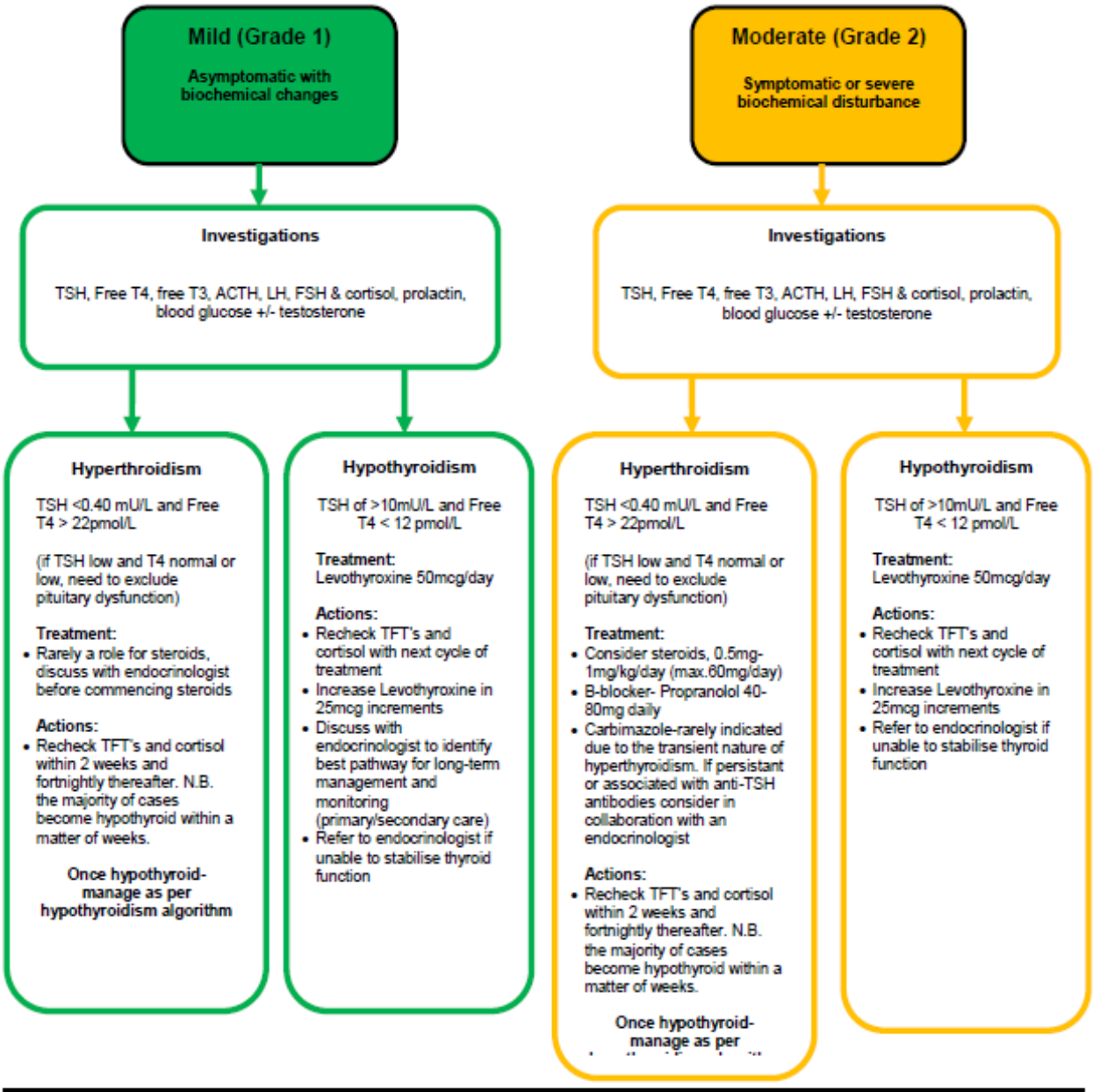
Having assessed the patient as per the guideline in the symptom management for adverse events it may be that referral to a specialist is required

Gastroenterology	Dr. Nic Hudson

Adapted from The Clatterbridge Cancer Centre NHS Foundation Trust Guidelines

Immune-Related Adverse Event: Endocrinopathies-Thyroid Dysfunction

Immunotherapy has been causatively associated with a number of endocrinopathies, including hypo/hyperthyroidism. Observational studies have shown that there is a typical pattern of thyroid specific biochemical disturbance presenting with asymptomatic hyperthyroidism, before return to normal levels for a brief period. This is nearly always followed by the development of, in some cases profound, hypothyroidism which is frequently persistent and requires long term thyroid replacement. Smaller subsets of patients develop isolated hypothyroidism over a period of weeks. Both groups appear to require long term replacement in a majority of cases.



Interrupt SACT immunotherapy until discussed with Acute Oncology Team. Please contact on-call oncology/haematology team for advice. Ensure that Acute Oncology/Haematology team are informed of admission.

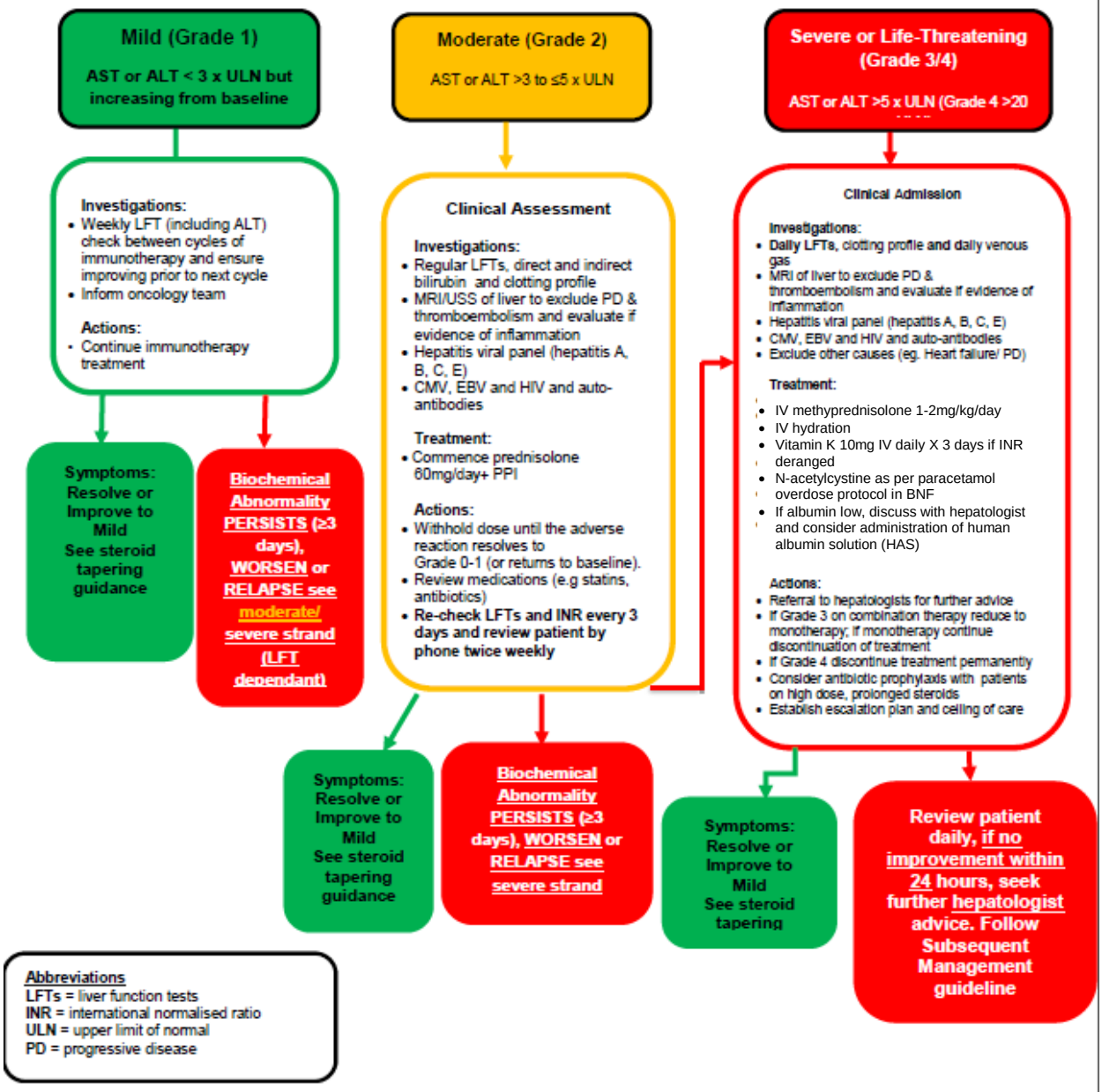
Having assessed the patient as per the guideline in the symptom management for adverse events it may be that referral to a specialist is required.

Endocrinology	Dr. Irfan Babar Dr. Munir Babar

Adapted from The Clatterbridge Cancer Centre NHS Foundation Trust Guidelines

Immune-Related Adverse Event: Hepatoxicity

Hepatic transaminases (ALT/AST) and bilirubin must be evaluated before each dose of immunotherapy, as early laboratory changes may indicate emerging immune-related hepatitis. Elevations in LFTs may develop in the absence of clinical symptoms. This guidance should be used in context of baseline LFTs and presence of known liver metastases. No dose adjustment is required for mild hepatic impairment but data is limited for use of these drugs in moderate/severe hepatic impairment and patients should be closely monitored for elevation in LFTs from baseline.
Prior to commencement of immunotherapy all patients should have LFTs checked



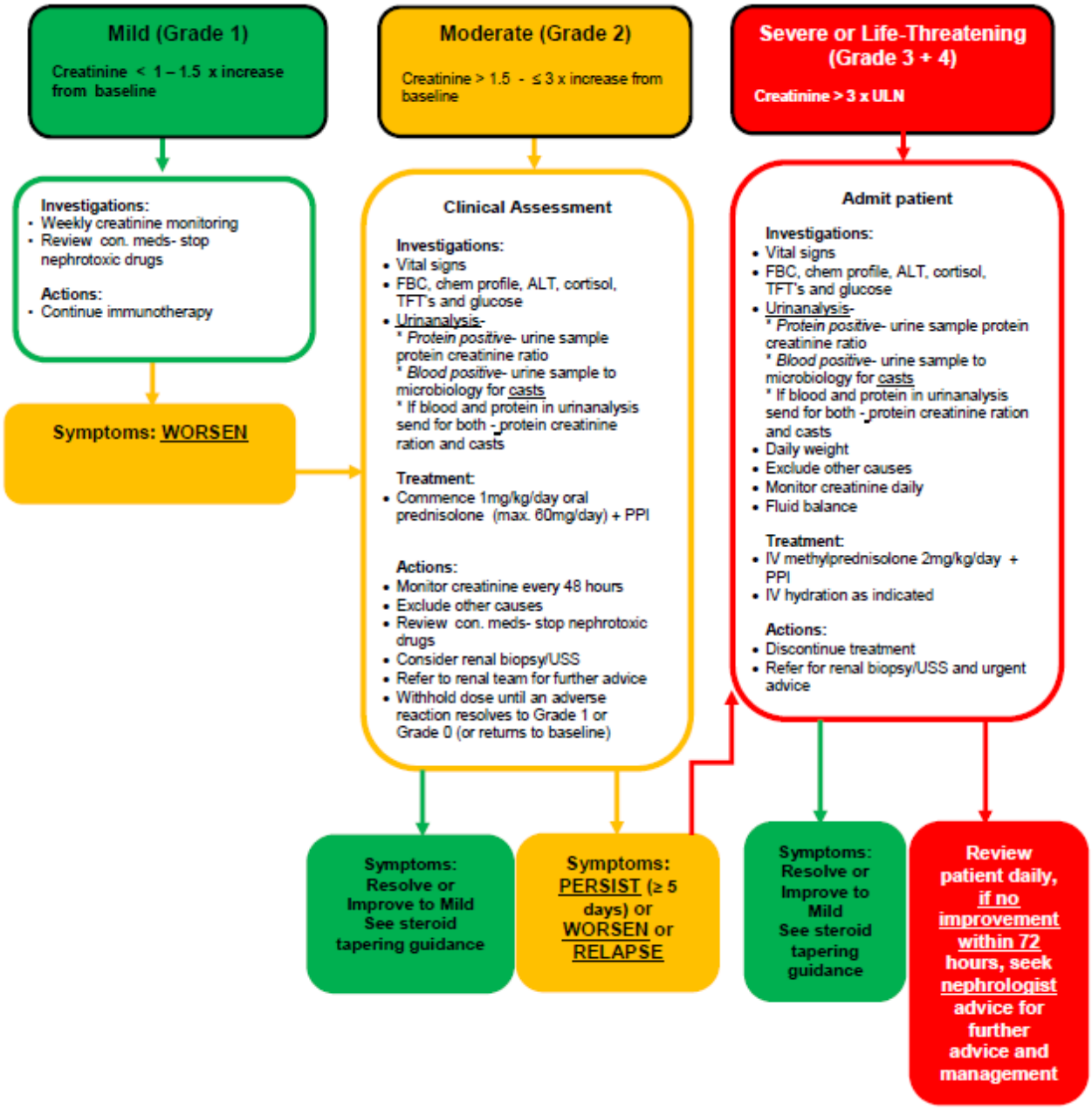
Abbreviations
LFTs = liver function tests
INR = international normalised ratio
ULN = upper limit of normal
PD = progressive disease

Interrupt SACT immunotherapy until discussed with Acute Oncology Team. Please contact on-call oncology/haematology team for advice. Ensure that Acute Oncology/Haematology team are informed of admission.

Adapted from The Clatterbridge Cancer Centre NHS Foundation Trust Guidelines

Immune-Related Adverse Event: Renal Toxicities

Elevated creatinine and biopsy confirmed tubulointerstitial nephritis and allergic nephritis have been infrequently observe following treatment with immunotherapy agents. The frequency of renal AEs may be greater with combination therapies than with monotherapy. Most cases were Grade 2 or Grade 3 and based on creatinine elevation. Patients with a history of RCC or prior nephrectomy do not appear to be at higher risk. Events were managed with corticosteroids and in all cases renal function partially or fully improved.



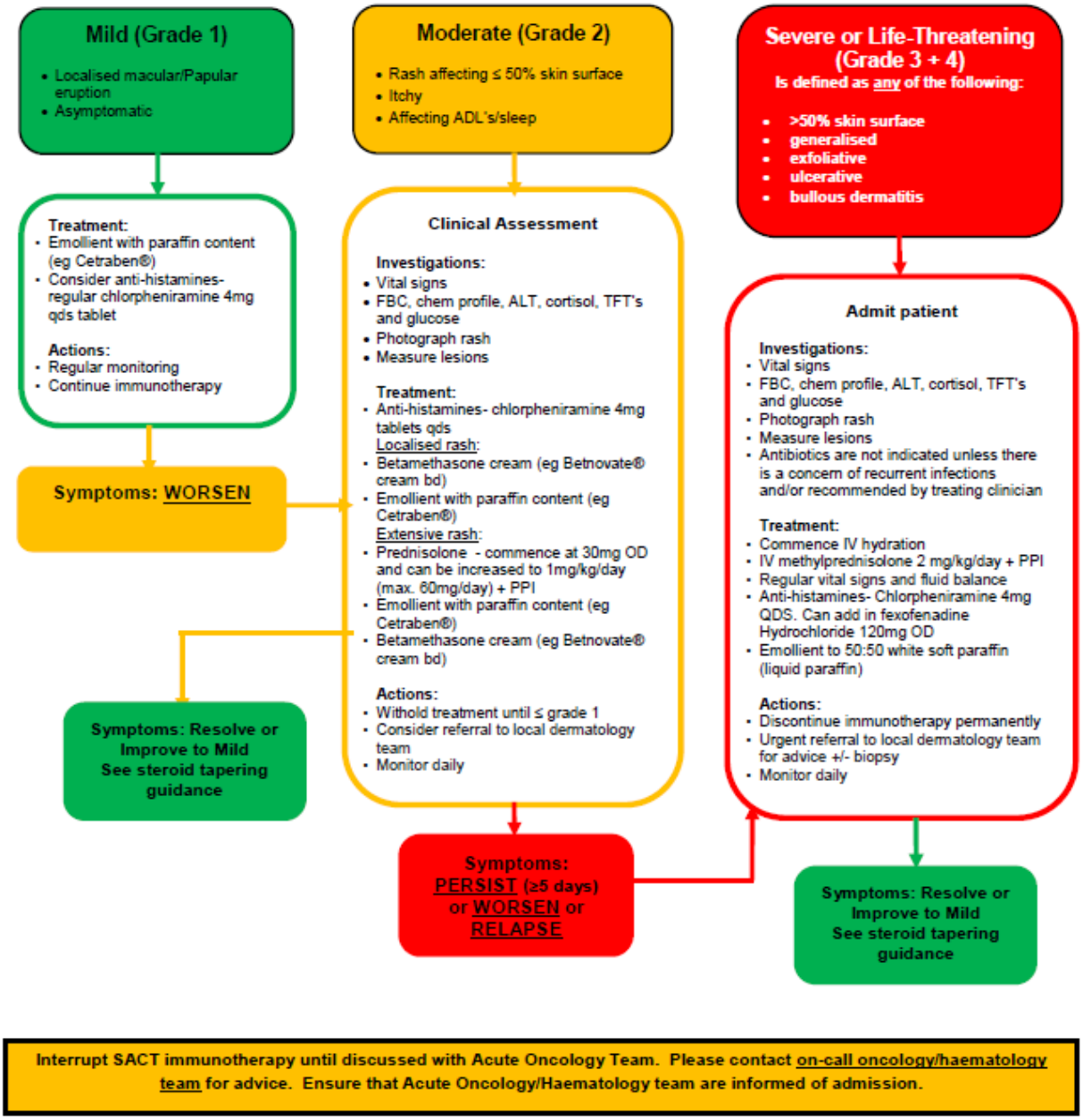
Having assessed the patient as per the guideline in the symptom management for adverse events it may be that referral to a specialist is required.

Renal	Dr. Martin Ferring

Adapted from The Clatterbridge Cancer Centre NHS Foundation Trust Guidelines

Immune-Related Adverse Event: Skin Toxicities

Immunotherapy administration is associated with immune-related adverse events (irAEs). Dermatological irAEs common and although they are typically mild to moderate in severity, if they are left unrecognised or untreated, they can become life-threatening. These toxicities can be managed effectively in almost all patients by using established guidelines that stress vigilance and the use of corticosteroids and other immunosuppressive agents when necessary.



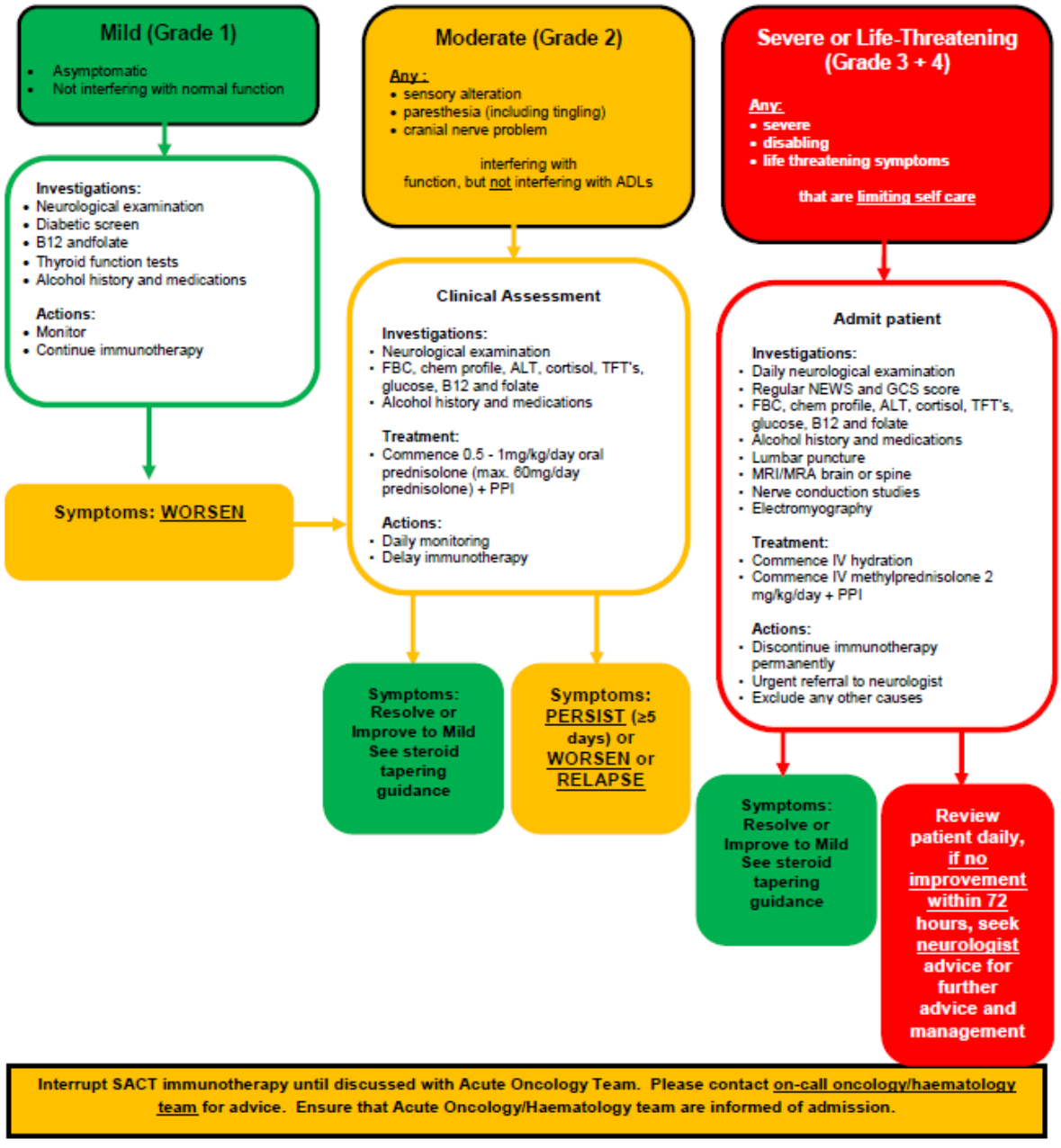
Having assessed the patient as per the guideline in the symptom management for adverse events it may be that referral to a specialist is required.

Dermatology	Dr. C.Leitner

Adapted from The Clatterbridge Cancer Centre NHS Foundation Trust Guidelines

Immune-Related Adverse Event: Neurological Toxicities

Immunotherapy administration is associated with immune-related adverse events (irAEs). Neurologic irAEs can manifest as central abnormalities (eg, asceptic meningitis, encephalitis) or peripheral sensory/motor neuropathies (eg, Guillain-Barre Syndrome). Early recognition and treatment of neurologic AEs is critical to its management. As neurologic symptoms can be common in patients with cancer, it is important that an evaluation/work-up distinguish between non-drug-related causes (eg, progression of disease, concomitant medications, infection) and a possible drug-related AE as the management can be quite different.



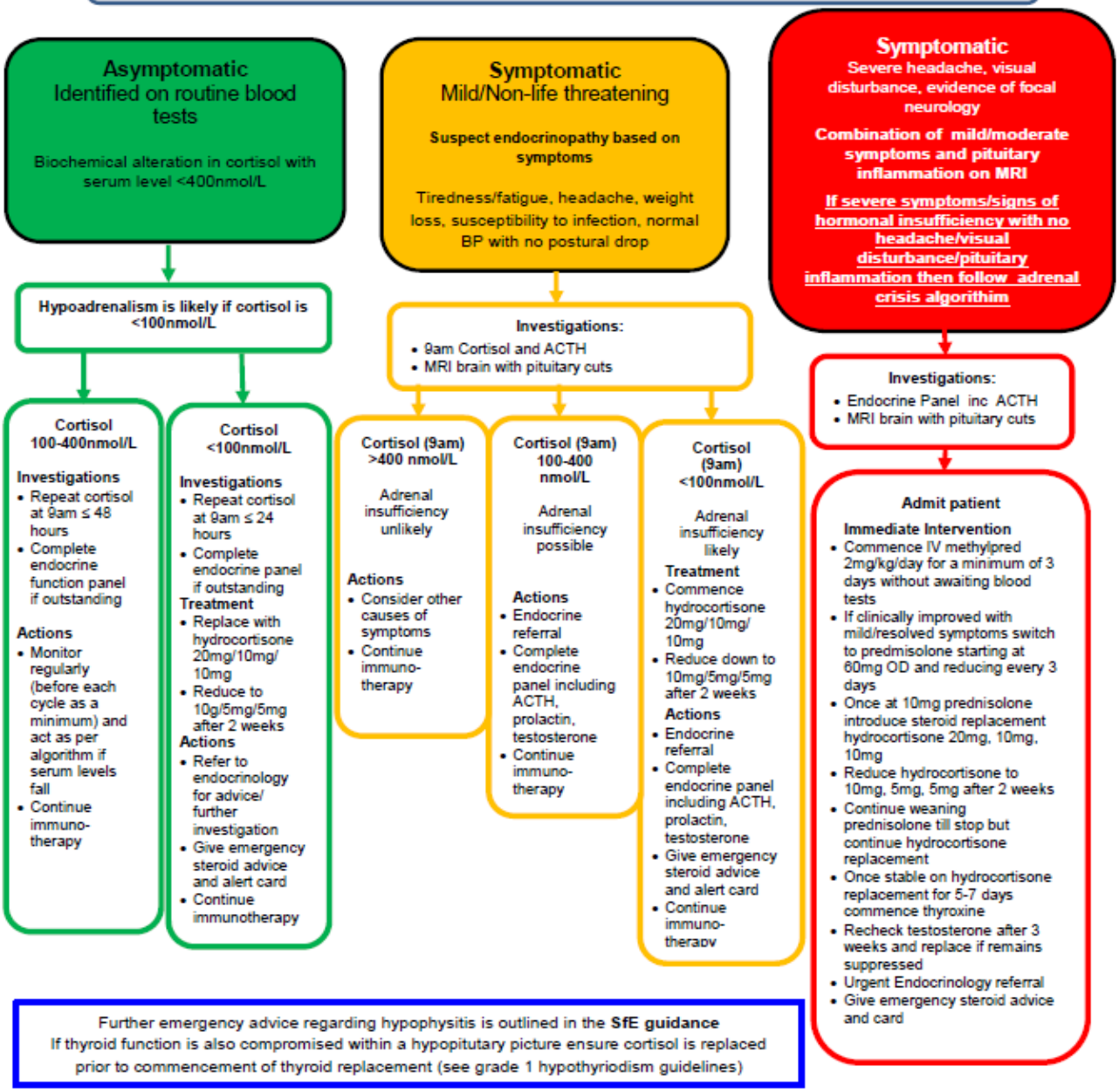
Adapted from The Clatterbridge Cancer Centre NHS Foundation Trust Guidelines

Immune-Related Adverse Event: Endocrinopathies- Hypophysitis

Immunotherapy has been causatively associated with a number of endocrinopathies that may present with nonspecific symptoms, which may resemble other causes such as brain metastasis or underlying disease.

Endocrine function panel:
U&E, LFT, TSH, Free T4, free T3, ACTH, LH, FSH & cortisol (between 9-11am if possible), prolactin, blood glucose +/- testosterone/oestrogen

CAUTION If the patient is on steroids (prednisolone/dexamethasone) then serum cortisol will likely be suppressed – please discuss with endocrinology team before commencing replacement



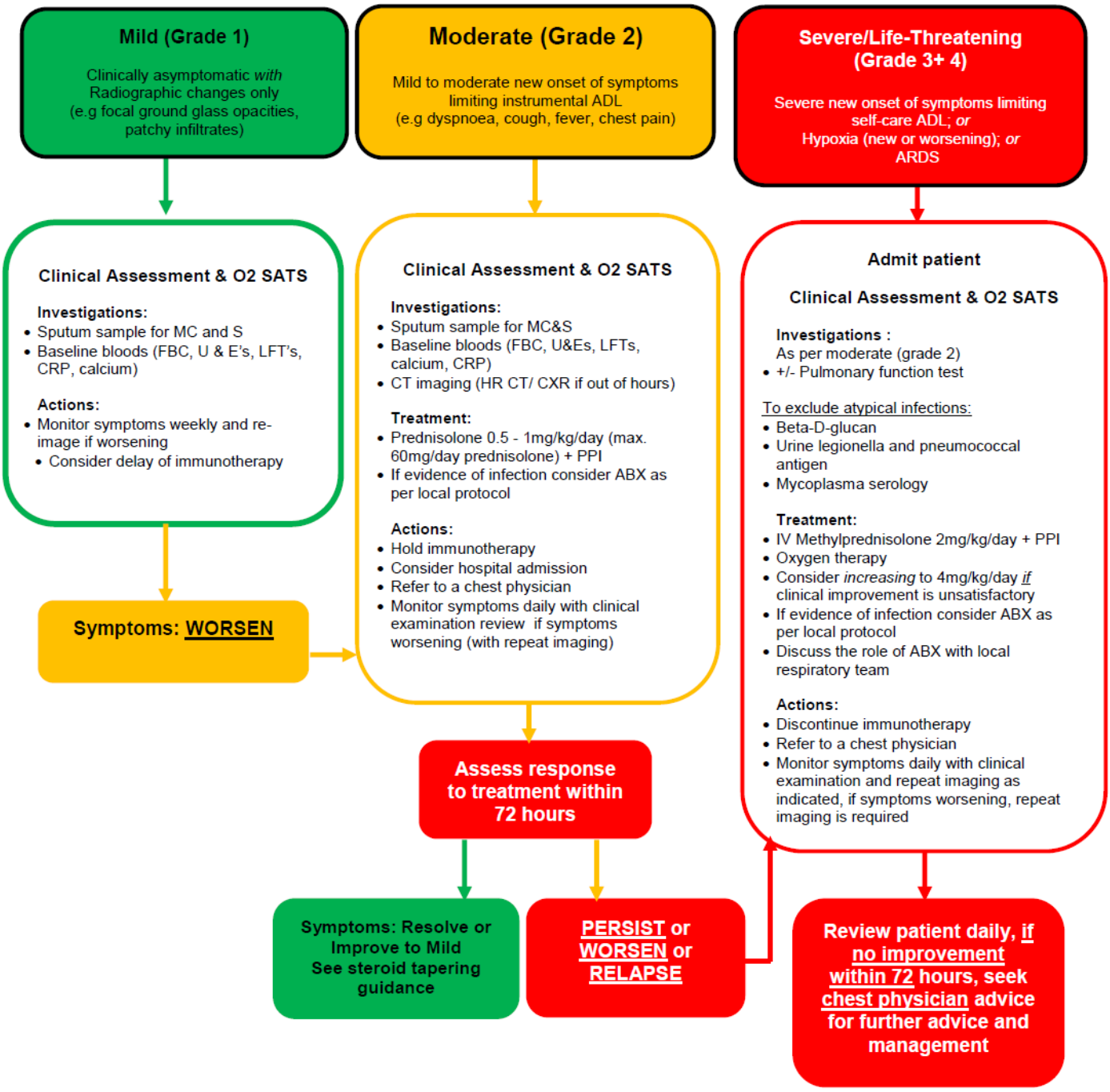
Having assessed the patient as per the guideline in the symptom management for adverse events it may be that referral to a specialist is required.

Respiratory	Dr. Kate Cusworth

THE CLATTERBRIDGE CANCER CENTRE NHS FOUNDATION TRUST

Immune-Related Adverse Event: Pneumonitis

Pulmonary irAEs have been observed following treatment with immunotherapy and have occurred after a single dose and after as many as 48 treatments. The frequency of pulmonary AEs may be greater with immunotherapy combination therapies than with monotherapy. The majority of cases reported were Grade 1 or Grade 2 and subjects presented with either asymptomatic radiographic changes (eg, focal ground glass opacities, patchy infiltrates) or with symptoms of dyspnoea, cough, or fever. Subjects with reported Grade 3 or Grade 4 pulmonary AEs were noted to have more severe symptoms, more extensive radiographic findings, and hypoxia.



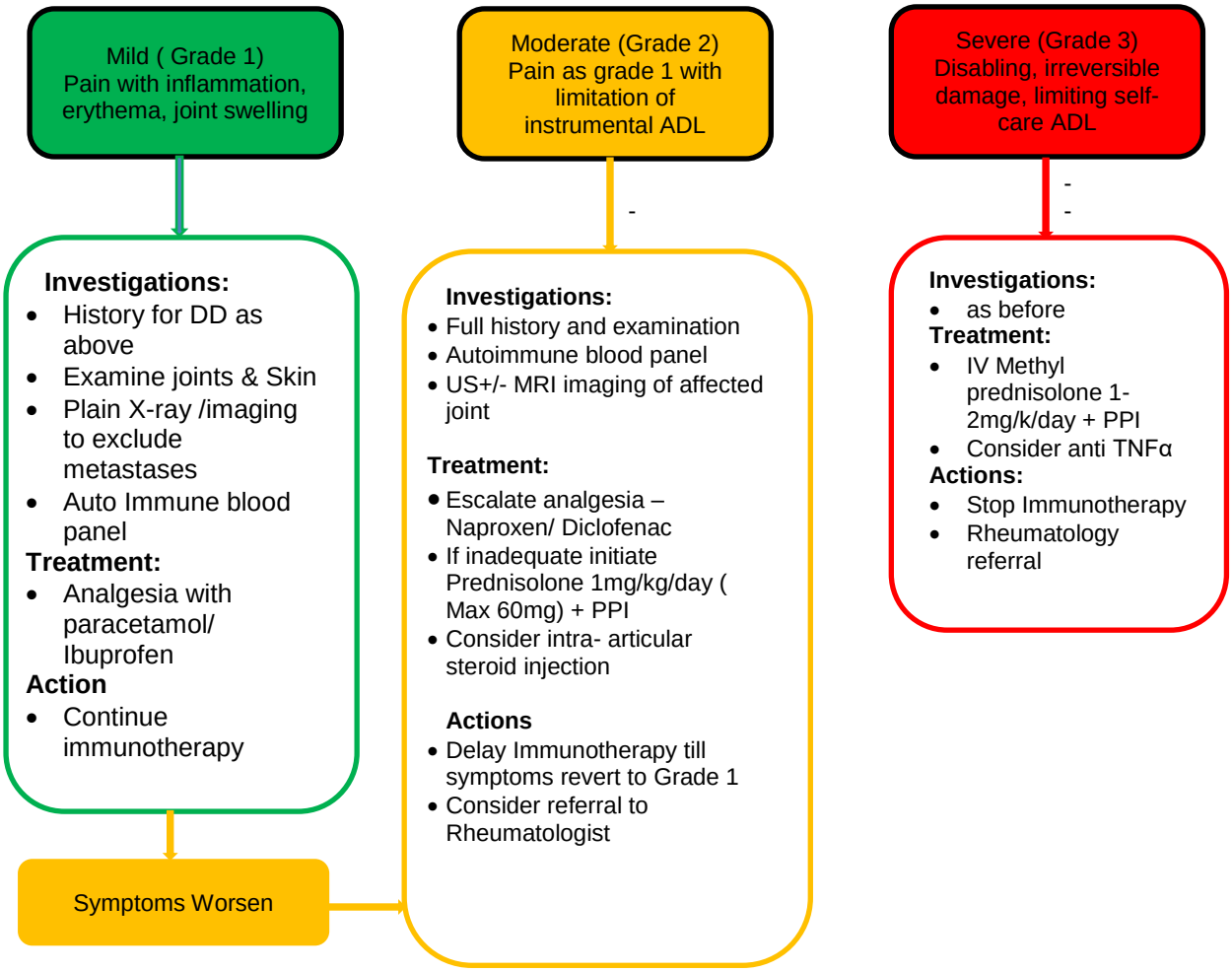
Interrupt SACT immunotherapy until discussed with Acute Oncology Team. Please contact on-call oncology/haematology team for advice. Ensure that Acute Oncology/Haematology team are informed of admission.

Worcestershire Acute Hospitals NHS Trust

Adapted From ESMO Guidelines

Immune -Related Adverse Event: Arthralgia

Immunotherapy administration can result in joint pain without associated swelling. It may occur in conjunction with myalgia, a common adverse event. DD to consider include arthritis, PMR and myositis. Due to paucity of literature on the management of this AE, rheumatology advice should be sought if symptoms are not responding to steroids



Having assessed the patient as per the guideline in the symptom management for adverse events it may be that referral to a specialist is required.

Rheumatology	Dr. Caroline Cardy

Adapted from The Clatterbridge Cancer Centre NHS Foundation Trust Guidelines

Steroid tapering guidance

Many patients will receive moderate- to high-dose steroid therapy for their immune-related toxicity for several weeks. Length of tapering is usually dictated by the severity of the irAE. Regular monitoring during tapering is strongly advised as there is an increased risk of irAE recurrence.

Oral steroid tapering:

- Initiate corticosteroid taper over 3-6 weeks

Tapering guidance:

- Monitor patient by telephone twice weekly during taper.
- Reduce prednisolone dose by 10mg every 3 days (as toxicity allows) until dose is 10mg/day.
- Once steroid dose is 10mg/day, reduce by 5mg for 5 days then stop.

ALL PATIENTS SHOULD HAVE A 9AM CORTISOL CHECKED WITHIN THE 5-7 DAYS FOLLOWING COMPLETION OF THEIR STEROID TAPER

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 60mg/day
- If following a re-flare and reintroduction of IV steroids reduce to 1mg/kg/day of prednisolone PO for 3 days then commence taper.

Upon discharge:

- Monitor patient by telephone twice weekly during taper.
- Reduce prednisolone dose by 10mg every 5 days (as toxicity allows) until dose is 10mg/day.
- Once steroid dose is 10mg/day, reduce by 5mg for 5 days then stop

Supportive measures:

Hyperglycaemia:
A baseline HbA1c should be requested at steroid initiation and random afternoon blood sugar monitoring (BM) should be undertaken whilst on treatment. If new hyperglycemia is detected, Endocrinology advice should be sought (many patients will require short term insulin in this setting). Pre-existing diabetes may require escalation in oral hypoglycemic agents or insulin.

Insomnia:
This is the most common steroid-related side effect. Sleep hygiene counselling is important. Patients may require short-term use of zopiclone (benzodiazepines should only be considered in rare circumstances for a max 3-5 days)

Osteoporosis:
Vitamin D and calcium levels should be taken at baseline and if low, replaced as appropriate. In patients on steroids for >3 months, or with pre-existing osteoporosis, a bone density scan and AdcalD3 and alendronate (or another bisphosphonate should be considered)

Infection:
In patients receiving the equivalent of prednisolone 25mg for ≥ 6 weeks PCP prophylaxis with co-trimoxazole (80/400mg Mon/Wed/Fri) should be considered

The oropharynx should be monitored for candidiasis and may require topical therapy such as Nystatin or oral fluconazole

If patients are on other immuno-modulatory agents e.g. Mycophenylate mofetil (MMF), consideration may be given to CMV prophylaxis with gancyclovir, especially if CMV IgG negative and lymphopenic.

5. ONGOING MANAGEMENT

Immunotherapy treatment should be withheld for patients suffering any grade 2 or above toxicity. The ongoing management will be co-ordinated by the consultant oncologist in charge of the patient's care together with the Immunotherapy CNS.

6. CONTACT NUMBERS FOR ADVICE

Acute Oncology Service 24 hours a day, 7 days a week	01905 760158 / 30049
Acute Oncology Nurse Practitioners (Mon-Fri 0900-1700)	Ext 30048 WRH Bleep 398 or 491 Alex Bleep 0192
Oncology Consultant On-call (24 hours)	Via Switchboard

7. TRAINING

Oncology Consultant presentation to acute medical staff and oncology medical team.

Training for nursing staff covering OOH, is by the Immunotherapy CNS

Training regarding administration and management of side effects is also included in the annual chemotherapy update for nurses.

8. REFERENCES

Nivolumab Dosing Administration and Safety Guide (2016) Bristol-Myers Squibb

Pembrolizumab Important Safety information to Minimise the Risk of Immune-Related Adverse Reactions (2016) Merck Sharp& Dohme

https://www.medicines.org.uk/emc/medicine/30602

https://www.medicines.org.uk/emc/medicine/30476

With Thanks for Nicola Jones UHB Chemotherapy lead for sharing Patient and GP letters

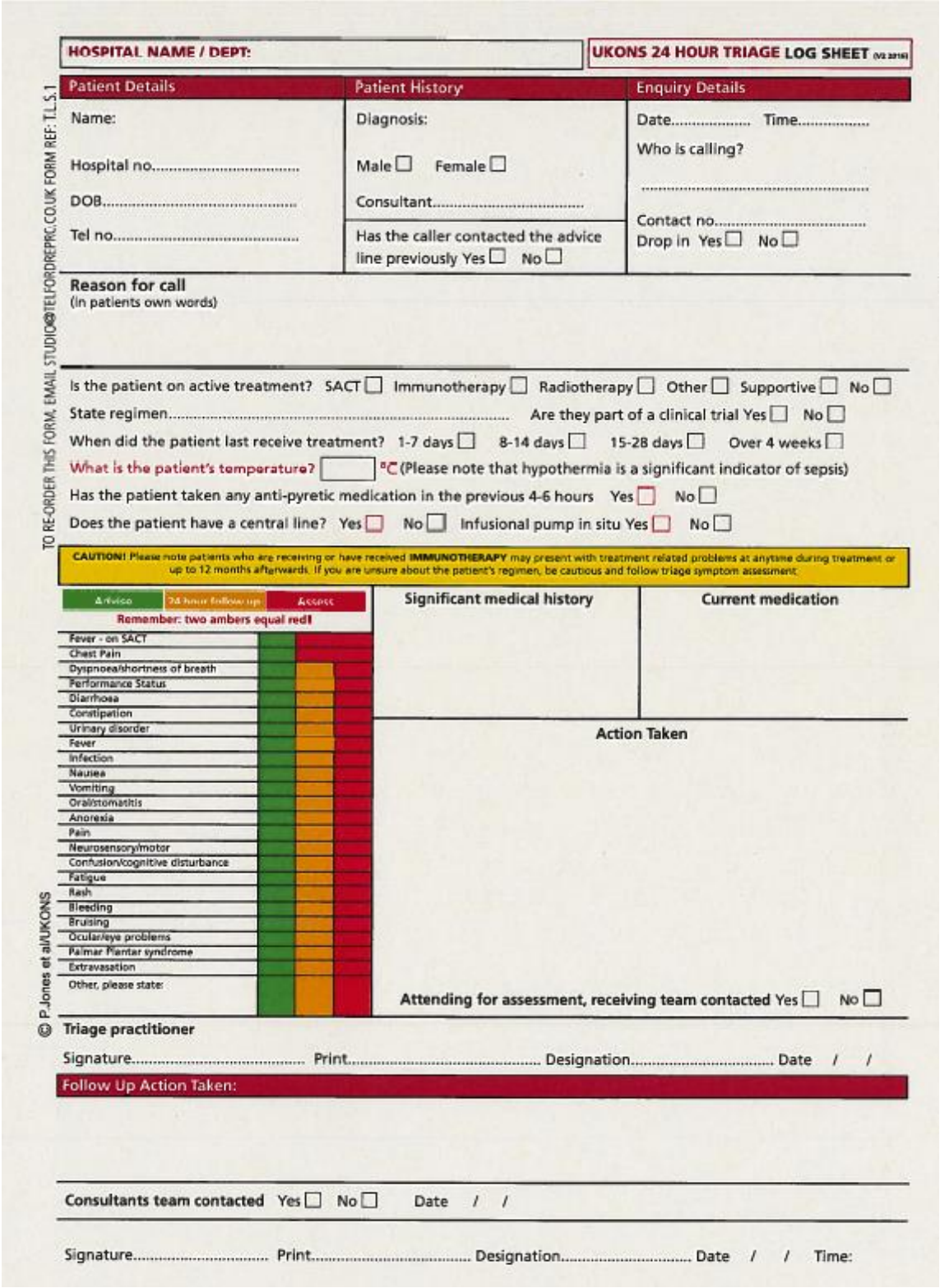
https://www.clatterbridgecc.nhs.uk/professionals/guidance-1

With thanks to Trudy Guinan lead Immunotherapy Nurse at Clatterbridge Cancer Centre for permission to use the Clatterbridge guidelines for Immunotherapy toxicities.

9. MONITORING TOOL

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	All patients with immune-related reactions receive appropriate and timely management	Audit to monitor compliance with guidance	After 6 months	Immunotherapy nurse / Lead Chemotherapy Nurse	Haematology/Oncology directorate	Annually

Appendix 1 – Triage Tool



HOSPITAL NAME / DEPT:

UKONS 24 HOUR TRIAGE LOG SHEET (V2.2015)

TO RE-ORDER THIS FORM, EMAIL STUDIO@TELFORDREPRO.CO.UK FORM REF: T.L.S.1

Patient Details	Patient History	Enquiry Details
Name: Hospital no..... DOB..... Tel no.....	Diagnosis: Male ☐ Female ☐ Consultant..... Has the caller contacted the advice line previously Yes ☐ No ☐	Date..... Time..... Who is calling? ..... Contact no..... Drop in Yes ☐ No ☐

Reason for call
(In patients own words)

Is the patient on active treatment? SACT ☐ Immunotherapy ☐ Radiotherapy ☐ Other ☐ Supportive ☐ No ☐

State regimen..... Are they part of a clinical trial Yes ☐ No ☐

When did the patient last receive treatment? 1-7 days ☐ 8-14 days ☐ 15-28 days ☐ Over 4 weeks ☐

What is the patient's temperature? ☐ °C (Please note that hypothermia is a significant indicator of sepsis)

Has the patient taken any anti-pyretic medication in the previous 4-6 hours Yes ☐ No ☐

Does the patient have a central line? Yes ☐ No ☐ Infusional pump in situ Yes ☐ No ☐

CAUTION! Please note patients who are receiving or have received **IMMUNOTHERAPY** may present with treatment related problems at anytime during treatment or up to 12 months afterwards. If you are unsure about the patient's regimen, be cautious and follow triage symptom assessment

Advice	24 hour follow up	Assess

Remember: two ambers equal red!

	Advice	24 hour follow up	Assess
Fever - on SACT			
Chest Pain			
Dyspnoea/shortness of breath			
Performance Status			
Diarrhoea			
Constipation			
Urinary disorder			
Fever			
Infection			
Nausea			
Vomiting			
Oral/stomatitis			
Anorexia			
Pain			
Neurosensory/motor			
Confusion/cognitive disturbance			
Fatigue			
Rash			
Bleeding			
Bruising			
Ocular/eye problems			
Palmar Plantar syndrome			
Extravasation			
Other, please state:			

Significant medical history

Current medication

Action Taken

Attending for assessment, receiving team contacted Yes ☐ No ☐

© P.Jones et al/UKONS

Triage practitioner

Signature..... Print..... Designation..... Date / /

Follow Up Action Taken:

Consultants team contacted Yes ☐ No ☐ Date / /

Signature..... Print..... Designation..... Date / / Time:

Appendix 2 – Patient letter for Immunotherapy

PATIENT LETTER

Please always carry this letter with you and show it to any Healthcare professional you are seen by.

Dear (Affix Sticker)

You are due to commence Immunotherapy under the care of …… (Consultant's name & place of work) on ……..

The Immunotherapy drug/s name is/are

Immunotherapy can cause serious side effects.

If you experience any of the following symptoms you should contact the Acute Oncology service from the alert card given to you.

- **Diarrhoea (more than 3 episodes of diarrhoea in a 24 hour period) or blood or mucus in stools, cramps or stomach pains**
- **Cough / Acute shortness of breath developed over a few days**
- **Extreme tiredness alongside dizziness**
- **Loss of limb movement**

There is a risk for developing Sepsis which could be life threatening. In case you develop any of the symptoms mentioned below, you should contact the Acute oncology service from the alert card.

- **Fever / temperature**
- **Any sign of infection**
- **Shivers, shakes or flu like symptoms**
- **Excessive bruising or bleeding from anywhere**
- **Generally feeling dreadful for no specific reason**
- **Severe vomiting, diarrhoea or exhaustion**

The acute oncology emergency number is 01905 760158.

Thank you

Signed …… Name……

Title……

Appendix 3 – SACT Information for GP

Systemic Anti-Cancer Treatment information for GP'S

Dear Doctor . . . . . .

RE:

The above patient is due to commence (Regimen) . . . . . .

This is an immune therapy and will be given on Ward . . . . . On (date) . . . . . .

under the care of Dr . . . . . .

Our main concern about patients receiving immune therapy relates to the risk of life threatening auto-immunity e.g. colitis, rash, hormone failure including pan-hypopituitarism, hepatitis, neuritis and pneumonitis.

Patients reporting adverse events including diarrhoea, abdominal pain, widespread rash, feeling generally unwell or more than usually fatigued should be assessed urgently. Specialist advice should be sought immediately via Acute Oncology Service
On- **01905760158**
24hrs a day.

ALL MEDICAL ENQUIRIES SHOULD GO THROUGH THE ON-CALL ONCOLOGIST via VIA SWITCHBOARD ON: 01905 763333

Please note for up to 6-18 months on completion of Immunotherapy a patient can develop an Immune related adverse event.

Steroids can affect the efficacy of this treatment please contact the oncall oncologist if this is needing to be considered for your patient.

Appendix 4

Fold line -->

Outside of card

Patient

NHS
Worcestershire Acute Hospitals NHS Trust

I am currently receiving

IMMUNOTHERAPY
Alert card

I am or have received Immunotherapy for cancer and may be at risk of Immune-related-Adverse Events which require urgent treatment.

Please contact the Acute Oncology service **01905 760158** and ask for switchboard to **Bleep 398**

On Presentation to the hospital, please follow the Management Instructions inside this card.

URGENT ADVICE FOR CLINICIANS

This patient is on immunotherapy and may be at risk of developing autoimmune side effects which require urgent treatment with corticosteroids.

These may include: diarrhoea and colitis, pituitary and thyroid dysfunction, hepatotoxicity, neuropathy, pneumonitis, renal toxicities and skin rashes.

Within Worcester Acute Hospitals Trust please refer to management of immune-related adverse events in immunotherapy guidelines on Intranet. For community or other Hospitals please contact the acute oncology service on the reverse of the card.

WHS 283 - Version 1

Fold line -->

Inside of card

Patient

Contact Telephone Number

Acute Oncology Service

01905 760158

24hrs a day

URGENT

You must contact the acute oncology service immediately if you experience any of the following:

- Diarrhoea or blood or mucus in stools, cramps or stomach pains -more than 3 episodes in a 24 hour period
- Cough / Acute shortness of breath -developed over a few days
- Extreme tiredness alongside dizziness
- Muscle weakness, pins & needles

Clinician

IMMUNE RELATED ADVERSE REACTIONS MANAGEMENT

Contact the On-Call Oncologist Immediately

Immune related adverse reactions can occur at anytime during treatment and up to 12 months after treatment has completed.

Please attach ID label or write details.

Patient's Name .....

Address .....

.....

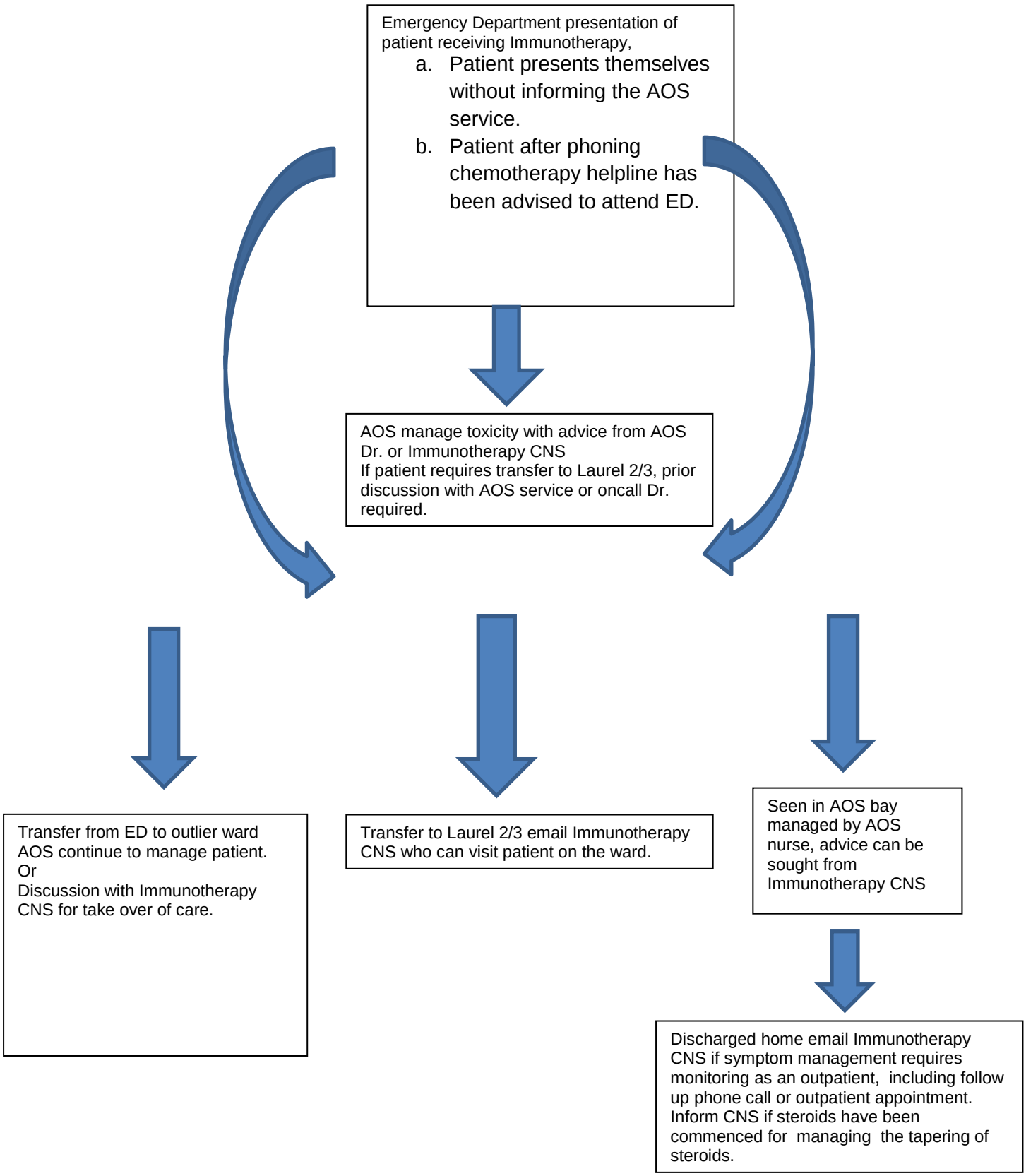
Telephone .....

Hospital Record Number .....

Name of Treatment .....

Appendix 5

Immunotherapy Pathway, Emergency Department presentation



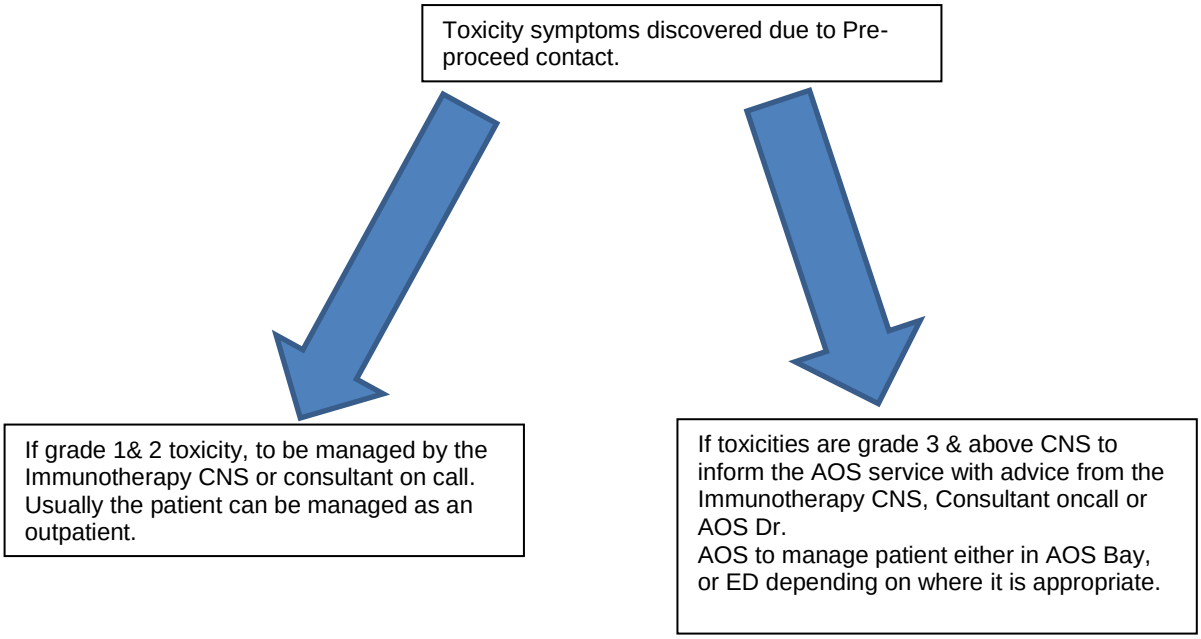
Immunotherapy Pathway, Clinic presentation

Seen by the Consultant in clinic or in Nurse led clinic.

Consultant to decide if toxicities are able to managed as an outpatient via Immunotherapy CNS.
Or
Need s admission.
If admission required Consultant

1. Informs the RMO if admission to ED /ward required.
2. Informs the AOS if patient needs to go the AOS bay for management by AOS.
3. If patient is able to be admitted to a bed On Laurel 2/3 Dr's on the ward informed of admission who will then clerk patient.

Immunotherapy pre proceed Toxicity



Supporting Document 1 – Equality Impact Assessment form

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust		Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
Date assessment completed			

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:**			
What is the aim, purpose and/or intended outcomes of this Activity?				
Who will be affected by the development & implementation of this activity?	❑ ❑ ❑	Service User Patient Carers	❑ ❑ ❑	Staff Communities Other _____

	❑	Visitors	❑	
Is this:	❑ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.				
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)				
Summary of relevant findings				

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age				
Disability				
Gender Reassignment				
Marriage & Civil Partnerships				
Pregnancy & Maternity				
Race including Traveling Communities				
Religion & Belief				
Sex				
Sexual Orientation				

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)				
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)				

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	
Date signed	
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	
2.	Does the implementation of this document require additional revenue	
3.	Does the implementation of this document require additional manpower	
4.	Does the implementation of this document release any manpower costs through a change in practice	
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval