183 Wattletree Rd Malvern Vic 3144 Australia p: +61 3 9508 1222 f: +61 3 9508 1098 www.cabrini.com.au

18 January 2023



Ms Sofia Hajdari Court Administration Officer Coroners Court of Victoria 65 Kavanagh Street Southbank VIC 3006

Dear Ms Hajdari

## Re: Investigation into the death of Heather Lucas COR 2020 001584

I write as follow up to your letter dated 20 October 2022, in which you requested a written response to the recommendations made by the Coroner.

A statement from Ms Sue Williams, Chief Executive, Cabrini Health is enclosed which addresses the information requested.

The following documents are also enclosed, and which are referenced in Sue Williams' letter:

- a) Cabrini policy on 'Rechallenge of Antineoplastic Agents' (Appendix A), and
- b) Patient Assessment Tool Infusion Treatment of Day Oncology MR 002F-05 (Appendix B)

I trust that the information provided is sufficient to address the Coroner's recommendations.

Please do not hesitate to contact me if you require any further information.

Yours sincerely

# M. Gordon

Melanie Gordon Clinical Risk Manager Cabrini Health

183 Wattletree Rd Malvern Vic 3144 Australia p: +61 3 9508 1222 f: +61 3 9508 1098 www.cabrini.com.au



Ms Sofia Hajdari Court Administration Officer Coroners Court of Victoria 65 Kavanagh Street Southbank VIC 3006

Dear Ms Hajdari

18 January 2023

# Re: Investigation into the death of Heather Lucas COR 2020 001584

Following the incident and recommendations from the coroner, Cabrini has completed a thorough review and revision of our policy on 'Rechallenge of Antineoplastic Agents'. We believe this revised policy now reflects best practice, is reliant on the Peter MacCallum clinical guideline on 'Rechallenge of Anti-cancer Agents' and is aligned with the US National Cancer Institute (NCI) guidelines.

The redrafted policy has been accepted and implemented by the Infusion Centre unit managers at our Brighton and Malvern campuses, and the head of our Oncology service. The policy is currently being considered for formal endorsement by the wider Oncology Medical Craft Group.

Cabrini has engaged our Director of Clinical Education to ensure all staff affected by these changes in policy and process understand the changes and are educated on the impact on their practice.

I provide the following response to the coroner's specific recommendations.

a. Cabrini Health review the grading scale utilised in the Platinum Hypersensitivity Reaction Guideline and consider implementing a recognised scale includes reference to more detailed signs and symptoms for each grade so as to facilitate a more accurate assessment of any reaction and grading with a view to reducing the possibility of underestimation of severity of assessment.

Cabrini has reviewed the literature on grading scales to classify reactions to chemotherapeutic medications.

This has identified the Cancer Therapy Evaluation Program from the US National Cancer Institute (NCI) grading scale for Common Toxicity Criteria, Version 2.0 (dated June 1, 1999).

- 0 = No adverse event or within normal limits
- 1 = Mild adverse event
- 2 = Moderate adverse event
- 3 = Severe and undesirable adverse event
- 4 = Life-threatening or disabling adverse event
- 5 = Death related to adverse event

This numeric scale has the following explanations, and these have been incorporated into Cabrini policy on 'Rechallenge of Antineoplastic Agents'.

Grade 1	Mild transient reaction; infusion interruption not indicated; intervention not indicated.
Grade 2	Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (eg, antihistamines, NSAIDs, narcotics [opioids], intravenous fluids); prophylactic medication indicated for less than or equal to 24 hours.
Grade 3	Prolonged (eg, not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for other clinical sequelae.
Grade 4	Life-threatening consequences; urgent intervention indicated.
Grade 5	Death.

As the Coroner notes, these descriptors do not provide detailed signs and symptoms that would allow clinical staff to consistently assign a category of reaction.

To meet this requirement Cabrini has adopted the hypersensitivity reaction descriptors from the Peter MacCallum clinical guideline.

NCI Grade 1-2: Mild to Moderate Reaction	NCI Grade 3-5: Severe Reaction
Pruritus	Anaphylaxis or anaphylactoid reaction
Facial flushing	Bronchospasm
Erythematous or urticarial rash	Facial/ tongue oedema
Palmar erythema	Angina or chest pain
Abdominal cramping	Tachycardia
Oedema of infusion arm	Respiratory arrest
Anxiety	Seizures
Diarrhoea	Acute Rigors
	Dyspnoea
	Hypotension
	Hypertension
	Extensive erythroderma or hives

b. Cabrini Health review their procedures to ensure that when a patient undergoes 'rechallenge' that an appropriately qualified, trained and equipped medical practitioner is at the bedside at least for administration of the drug and for a period within which any adverse reaction would be expected to manifest taking into account that any patient who has previously experienced grade 2 or greater reactions will not be re-challenged.

Cabrini's revised policy requires that all rechallenges following a mild to moderate reaction (NCI Grade 1 - 2) are undertaken at our Malvern Infusion Centre. This will ensure there is an appropriately qualified, trained and equipped medical practitioner at the bedside at least for administration of the drug and for a period within which any adverse reaction would be expected to manifest.

The policy incorporates the process for referral and arrangement for rechallenge.

c. Cabrini Health review its record keeping processes and procedures including the Adverse Drug Reaction System and ensure that all adverse drug reactions are recorded in a timely fashion on all databases, written and electronically held including in the patient's medical record that are accessible by clinical staff and explicitly considered before any re-challenge.

Cabrini has reviewed the process and location for recording adverse drug reactions.

At present these reactions can be independently recorded in the patient admission system (WebPAS), the medication management system (MedChart), the chemotherapy management system (CHARM) and on the patient's physical medical record.

Cabrini has determined that the medication management system should be the source of truth for adverse drug reaction recording.

We have worked with our application supplier (Dedalus) to design a new interface between our various applications, which will ensure that the allergy information is entered in MedChart and this information will be displayed on WebPAS screens. This is a significant update, planned for implementation in July 2023. We continue to work on an interface between MedChart and CHARM.

Processes have been implemented to ensure the physical medical record reflects what is recorded in MedChart.

d. The Patient Assessment Tool – Day Oncology tool be amended to allow explicit recording of allergic reactions so that staff are not required to only rely on a patient informing them of a previous allergic reaction.

Following the death of Mrs Lucas and Cabrini's subsequent review of its forms and policies, the Patient Assessment Tool – Day Oncology (Appendix B) was amended to allow explicit recording of allergic reactions.

In the "Allergy List" section the form now includes the questions:

## Reaction to any previous therapy

Have you had a previous reaction to the prescribed chemotherapy treatment? Has your doctor discussed reactions to therapy and the possible need for rechallenge?

e. Cabrini Health implement these processes and procedures across all its campuses.

The revised policy and updated IT applications will be implemented across both Malvern and Brighton campuses where our chemotherapy patients receive treatment.

I wish to thank the Coroner for providing the opportunity to respond to these recommendations.

Yours Sincerely

Angen acc

Sue Williams Chief Executive Officer



TITLE Platinum Agents: Acute Reaction Management & I	Rechallenge Guideline
--	-----------------------

TARGET AUDIENCE Medical, Nursing and Pharmacy

**SCOPE** All Cabrini staff involved in the treatment of a patient who has experienced an infusion or hypersensitivity reaction to antineoplastic agents – particularly platinum agents.

#### CONTENTS

	PURPC	DSE	2
	DEFINI	ITIONS	2
		ION GRADING	
	CLASSI	IFICATION OF REACTIONS	3
	ACUTE	MANAGEMENT	4
		ALLENGE POLICY	
	DOCUI	MENTATION	5
	BOOKI	NGS	5
	STAFF	RESPONSIBILITIES	6
1.	PLATI	INUM COMPOUNDS	
	1.1	Introduction	7
	1.2	Carboplatin	8
	1.3	Cisplatin	8
	1.4	Oxaliplatin	9

Prompt Doc No: <#doc_id> Version: <#ver_num>	Date Loaded onto Prompt: <#issue_date>	Last Reviewed Date: <#last_review_date>
Next Review Date: <#next_review_date>	UNCONTROLLED WHEN DOWNLOADED	Page 1 of 10



#### PURPOSE

This guideline provides guidance to clinical staff for rechallenging of patients following infusion or hypersensitivity reactions to platinum agents. It has been adapted from the *Peter MacCallum Cancer Centre Rechallenge of Anti-Cancer Agents (clinical guideline)*.

**For Management of Anaphylactic Reactions** see *Management and Reporting of Anaphylaxis available* <u>on PROMPT</u>. For acute management of infusion related/ hypersensitivity reactions see <u>Acute</u> <u>Management</u> in this document.

#### DEFINITIONS

## **Rechallenge:**

To treat a patient with an agent after they have experienced a reaction (of any grade) to the agent.1,2

## **Infusion Reaction:**

Infusion reactions can be caused by all antineoplastic agents. Infusion reactions are often referred to as hypersensitivity reactions, however, not all infusion reactions have a true immunologic mechanism.

## Hypersensitivity Reaction:

Hypersensitivity is defined as a state of altered reactivity where the body reacts with an exaggerated or inappropriate immune response to what is perceived to be a foreign substance.

#### Anaphylaxis:

Anaphylaxis is characterized by an acute inflammatory reaction resulting from the release of histamine and histamine-like substances from mast cells, causing a hypersensitivity immune response typically mediated by immunoglobulin E (IgE).

# Grading of Infusion Reactions:

National Cancer Institute, Common Terminology Criteria for Adverse Events (CTCAE).

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild to Mode	rate Reactions	9	Severe Reactions	
Responds prompt	ly to symptomatic	Prolong	ed or recurrent sympt	oms
manag	gement			
Mild transient reaction; infusion interruption not indicated; intervention not indicated	Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (eg, antihistamines, NSAIDs,	Prolonged (eg, not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of	Life-threatening consequences; urgent intervention indicated	Death
	narcotics [opioids], intravenous fluids); prophylactic medication indicated for less than or equal to 24 hours	symptoms following initial improvement; hospitalization indicated for other clinical sequelae		

Prompt Doc No: <#doc_id> Version: <#ver_num>	Date Loaded onto Prompt: <#issue_date>	Last Reviewed Date: <#last_review_date>
Next Review Date: <#next_review_date>	UNCONTROLLED WHEN DOWNLOADED	Page 2 of 10



Typical Signs and Symptoms	Typical Signs and Symptoms
Pruritus	Anaphylaxis or anaphylactoid reaction
Facial flushing	Bronchospasm
Erythematous or urticarial rash	Facial/ tongue oedema
Palmar erythema	Angina or chest pain
Abdominal cramping	Tachycardia
Oedema of infusion arm	Respiratory arrest
Anxiety	Seizures
Diarrhoea	Acute Rigors
Mild Fever	Dyspnoea
Muscular pain	Hypotension
	Hypertension
	Extensive erythroderma or hives

The clinical features of anaphylaxis and standard infusion reactions overlap; however, certain signs and symptoms are highly suggestive of anaphylaxis: urticaria, repetitive cough, wheeze, throat tightness/change in voice, and hypotension.

Fever and prominent muscular pain are NOT features of anaphylaxis, and the presence of these signs and symptoms suggests the reaction is a standard infusion reaction.

# Oxaliplatin may cause Laryngopharyngeal dysesthesia which can be confused with bronchospasm.

Laryngopharyngeal dysesthesia <u>typically occurs on exposure to the cold/ changes in temperature</u> during or within 48 hrs following treatment with oxaliplatin.

This reaction may cause the patient to have subjective sensations of difficulty swallowing or breathing without objective evidence of laryngopharyngeal dysfunction or respiratory distress.

CTCAE	Acute Management of Reactions to Platinum Agents			
Grade				
Grades 2-4	NURSINGImmediately stop infusionPlace patient in recumbent positionAdminister oxygenMonitor vital signs frequentlyNotify medical teamAdminister hydrocortisone and promethazine per PRN order	MEDICAL Suggested PRN Orders: • Hydrocortisone 250mg IV • Promethazine 12.5mg IV		
Grade 1	Continued observation until event fully settles Consider rechallenge with slower infusion rate and increased premedications If reaction recurs, abandon treatment			
Grade 2	<ul> <li>NURSING</li> <li>Notify medical team</li> <li>Administer nebulised salbutamol, hydrocortisone and promethazine per PRN order</li> <li>If unable to contact medical team in a timely manner, initiate MET call.</li> </ul>	MEDICAL If symptoms not settling in 30 min, Suggested PRN orders: IV hydrocortisone 100mg IV promethazine 12.5mg Abandon treatment		

Prompt Doc No: <#doc_id> Version:	Date Loaded onto Prompt: <#issue_date>	Last Reviewed Date: <#last_review_date>
<#ver_num>		
Next Review Date: <#next_review_date>	UNCONTROLLED WHEN DOWNLOADED	Page 3 of 10



Grades 3-4	NURSING	NURSING
	Initiate MET call	MEDICAL /MICA PARAMEDIC
	IM Adrenaline (epinephrine) 1:1000	If inadequate response or deterioration
	0.5 mL (ADMINISTER IMMEDIATELY) –	consult with medical staff and start an
	requires medical order	intravenous adrenaline infusion (with
	Administer nebulised salbutamol	specialist supervision): Mix 1 mL of
		1:1000 adrenaline in 1000 mL of normal
	BRIGHTON	saline. Start infusion at 5 mL/kg/hour (0.1 microgram/kg/min) and titrate rate
	<ul> <li>If inadequate response call 000 to initiate transfer to ICU.</li> </ul>	according to response. Monitor
	initiate transfer to ICU.	continuously.
		<ul> <li>If adrenaline (epinephrine) is ineffective</li> </ul>
		at resolving upper airway obstruction,
		administer nebulised adrenaline (5 mL,
		i.e. 5 ampoules of 1:1000) and intubate.
		• For persistent hypotension/shock, give
		normal saline (maximum 50 mL/kg in the
		first 30 min) and intravenous glucagon
		bolus of 1–2 mg in adults. This may be
		repeated or followed by an infusion of
		1–2 mg/hour in adults
		Transfer to Intensive Care
		Define a frequency of observations

# POLICY

The reported or documented history of an infusion reaction does not prohibit the rechallenge of the offending agent (unless specified). Rechallenge should be guided by the severity, grade and features of the previous reaction and must be undertaken under medical supervision at Malvern.

Rechallenges following Severe Reactions (Grade 3-5) to platinum compounds must not be undertaken. Rechallenges following Grade 2 reactions must be carefully considered by the treating oncologist to evaluate the benefit of continuing treatment and available alternatives.

#### Documentation

All adverse drug reactions are to be recorded in a timely fashion on all databases, written and electronically held, including in the patient's medical record that are accessible by clinical staff as per the 'Patient Allergies and Adverse Drug Reactions' Policy. This includes:

- CHARM
- PAS
- Med Chart (where applicable)
- RiskMan
- Medical Record (Allergy and ADR Clinical Alert Divider)
- Suspected Adverse Drug Reaction (ADR) Notification form MR065D

Prompt Doc No: <#doc_id> Version:	Date Loaded onto Prompt: <#issue_date>	Last Reviewed Date: <#last_review_date>
<#ver_num>		
Next Review Date: <#next_review_date>	UNCONTROLLED WHEN DOWNLOADED	Page 4 of 10



## All documented reactions must be explicitly considered before any re-challenge.

## **Platinum Rechallenge - Bookings**

A rechallenge to a platinum agent must be performed within the infusion centre at the <u>Cabrini Malvern</u> campus where an appropriately qualified, trained and equipped medical practitioner must be at the bedside at least for administration of the drug and for a period within which infusion reactions are likely to occur (typically 30 minutes).

Rechallenges to other antineoplastic agents (e.g. Taxanes, Monoclonal Antibodies and Aspariginase products) should be considered on a case by case basis and performed at either campus (Malvern or Brighton) at the discretion of the referring oncologist. Where escalation of medical support is required, rechallenge at Malvern rather than Brighton is recommended.

- The referral must clearly indicate that treatment is for rechallenge the grade of the previous reaction (e.g. PHx CTCAE Grade 1) should be outlined on the referral that is sent to the infusion centre at Cabrini Malvern
  - Ph: 9508 1821 Fax: 95081957
- 2. It must be made clear at the time of booking that the infusion will be a rechallenge to ensure sufficient staff (medical and nursing) will be available to supervise and observe the patient.
- 3. Any extra requirements (e.g. extended infusion times, pre-medications, scalp cooling, increased observations) must be communicated with the Malvern Infusion Centre (Day Oncology) in advance.

#### Responsibilities

#### Nursing staff:

- Upon admission for the infusion of antineoplastic agents, each patient must be interviewed by the infusion nurse to identify any history of suspected or known allergies or infusion reactions.
- The infusion nurse is to cross check the patient reported allergies and/or reaction history in all relevant manual and electronic health management systems including CHARM, PAS and the Medical Record (Allergy & ADR Clinical Alert Divider).
- All identified allergies or reactions must be documented in the MR 002F-05 (Patient Assessment Tool –Infusion Treatment/ Day Oncology) which is to be filed in the patients 'medical record.
- If there is a discrepancy in the reported and documented allergy/ reaction history that the prescribing doctor should be notified.

#### Medical Staff:

- Prior to prescribing or pursuing rechallenge of antineoplastic agents the prescriber must consider all information available to them to determine whether it is appropriate for the patient. It is expected that relevant systems (CHARM, PAS, MedChart, Medical Record) are checked for any allergies or reactions.
- Ensure informed consent is explicitly obtained for the purpose of rechallenge to the specific agent, outlining all risks and alternatives. Evidence of informed consent must be documented in the medical record and an encounter note placed in CHARM.

Prompt Doc No: <#doc_id> Version: <#ver_num>	Date Loaded onto Prompt: <#issue_date>	Last Reviewed Date: <#last_review_date>	
Next Review Date: <#next_review_date>	UNCONTROLLED WHEN DOWNLOADED	Page 5 of 10	



- Record any suspected or known adverse infusion reactions in the CHARM Chemotherapy prescribing system and other systems as described under <u>documentation</u> section above.
- Where appropriate the responsible doctor should also complete a
  - Suspected Adverse Drug Reaction (ADR) Notification MR065D
  - Therapeutic Goods Administration (TGA) Reaction Reporting Form
- Where appropriate a Resuscitation Plan MR004 should be completed by treating Doctor
- In the event of a rechallenge, an appropriately qualified and equipped medical practitioner must be present at the bedside. This may be the treating doctor or delegated to another physician or an advanced trainee familiar with the rechallenge protocol.
- Medical staff to complete CHARM chart and document appropriate premedications for administration to minimise reaction as indicated in section 1 under individual platinum agents.

 Prompt Doc No: <#doc\_id> Version:
 Date Loaded onto Prompt: <#issue\_date>
 Last Reviewed Date: <#last\_review\_date>

 <#ver\_num>
 UNCONTROLLED WHEN DOWNLOADED
 Page 6 of 10



## 1. PLATINUM COMPOUNDS

## **1.1 Introduction**

Infusion reactions including hypersensitivity and anaphylactic reactions have been reported with the platinum containing compounds Carboplatin, Cisplatin and Oxaliplatin. The most common drug to cause hypersensitivity reaction is Carboplatin. The risk of hypersensitivity is increased in patients who have had previous treatment with a platinum agent and with multiple doses or cycles of the same platinum agent but can still rarely occur during or after the initial dose. Cross sensitivity is seen, but is not absolute and with appropriate precautions, patients experiencing a hypersensitivity reaction to one platinum agent have tolerated another

#### **Onset and Risk Factors**

- Patients who have had a previous platinum reaction.
- Both anaphylaxis and infusion related reactions usually occur during, or within a few hours of administration. Platinum reactions characteristically occur within minutes of commencing the infusion.
- Numbers of prior cycles of platinum and cumulative dose of platinum are the major risk factors for development of platinum allergic reaction.

## 1.2 Carboplatin

Patient groups at higher risk for reactions to carboplatin include individuals who have had multiple infusions with carboplatin, with relapsed disease, those with BRCA mutations, and children with brain tumours.

#### Carboplatin: Rechallenge

#### Severe Reaction (CTCAE grades 3-4)

The manufacturer <u>does not recommend</u> the use of carboplatin following hypersensitivity or severe allergic reaction with carboplatin or other platinum containing compounds (e.g. cisplatin).

- 1. If clinically appropriate, patients should be changed to alternate agent/s (other than a platinum agent)
- 2. Consult with the patient's consultant to agree on a plan

Ensure hypersensitivity reaction is documented as an allergy/adverse drug reaction as outlined in <u>documentation section</u> above.

# Mild to Moderate Reaction (CTCAE grades 1-2)

Consider whether continued treatment on the same day is appropriate or retreatment on a future date.

- 1. Consult with the patient's consultant to agree on plan depending on severity of reaction
- 2. Prophylactic corticosteroid and antihistamine use is recommended for further dosing A *suggested* protocol includes:
  - Oral loratidine 10 mg/day for 3 days prior to infusion + dexamethasone 4 mg bd for 1 to 3 days prior to infusion
  - IV hydrocortisone 100 mg on the day of infusion

Prompt Doc No: <#doc_id> Version:	Date Loaded onto Prompt: <#issue_date>	Last Reviewed Date: <#last_review_date>
<#ver_num>		
Next Review Date: <#next_review_date>	UNCONTROLLED WHEN DOWNLOADED	Page 7 of 10



- o Oral Nizatidine 150 mg 30 minutes prior to commencement of Carboplatin
- IV /oral promethazine 25 mg 30 minutes prior to commencement of Carboplatin
- 3. Consider increasing the administration time to 3 hours, instead of the usual 30 minutes

Ensure hypersensitivity reaction is documented as an allergy/adverse drug reaction as outlined in <u>documentation section</u> above.

## 1.3 <u>Cisplatin</u>

Patient groups at higher risk for reactions to carboplatin include individuals who have had multiple infusions with carboplatin, with relapsed disease, those with BRCA mutations, and children with brain tumours.

It should also be noted that Cisplatin is associated with nephrotoxicity and strategies to prevent nephrotoxicity in patients must also be considered. Risk factors for nephrotoxicity with cisplatin include high doses of cisplatin, previous exposure to cisplatin and pre-existing kidney damage.

# **Cisplatin: Rechallenge**

## <u>Severe reaction (CTCAE grades 3-4)</u>

The manufacturer <u>does not recommend</u> rechallenging cisplatin following hypersensitivity reaction with cisplatin or any other platinum containing compounds.

- 1. Consideration may be given to substitution with alternate agents, other than platinum agents
- 2. Occasionally patients who experienced anaphylactic reactions have been safely re-treated with cisplatin following pre-treatment with corticosteroids and / or antihistamines; however such prophylaxis is not uniformly effective in preventing recurrence and hence is not recommended following a severe reaction.

Ensure hypersensitivity reaction is documented as an allergy/adverse drug reaction as outlined in <u>documentation section</u> above.

# Mild to Moderate Reaction (CTCAE grades 1-2)

Consider whether continued treatment on the same day is appropriate or retreatment on a future date.

- 1. Consult with the patient's consultant to agree on plan depending on severity of reaction
- 2. Prophylactic corticosteroid and antihistamine use is recommended for further dosing
- 3. A suggested protocol at includes:
  - Oral loratidine 10 mg/day for 3 days prior to infusion +/- dexamethasone 4 mg bd for 3 days prior to infusion
  - IV hydrocortisone 100 mg on the day of infusion
  - Oral Nizatidine 150 mg 30 minutes prior to commencement of cisplatin
  - o IV /oral promethazine 25 mg 30 minutes prior to commencement of cisplatin

Ensure hypersensitivity reaction is documented as an allergy/adverse drug reaction as outlined in <u>documentation section</u> above.

Prompt Doc No: <#doc_id> Version:	Date Loaded onto Prompt: <#issue_date>	Last Reviewed Date: <#last_review_date>
<#ver_num>		
Next Review Date: <#next_review_date>	UNCONTROLLED WHEN DOWNLOADED	Page 8 of 10



# 1.4 Oxaliplatin

As with other platinum agents, the incidence of a reaction to the agent Oxaliplatin increases with multiple cycles or repeated courses of treatment.

Acute <u>Laryngopharyngeal dysesthesia</u>, is a common side-effect of Oxaliplatin (but no other platinum agent), occurring to some degree in greater than 30% of patients and in severe form in 1-2%. The manufacturer suggests that extending subsequent infusion times from 2 to 6 hours to reduce toxicity.

## **Oxaliplatin: Rechallenge**

## Severe Reaction (CTCAE grades 3-4)

The manufacturer states the use of oxaliplatin is contraindicated in patients with history of severe reaction or hypersensitivity reaction to oxaliplatin any of the excipients or other platinum compounds.

Ensure hypersensitivity reaction is documented as an allergy/adverse drug reaction as outlined in <u>documentation section</u> above.

Mild to Moderate Reaction (CTCAE grades 1-2)

Consider whether continued treatment on the same day is appropriate or retreatment on a future date.

- 1. Consult with the patient's consultant to agree on plan depending on severity of reaction
- 2. Prophylactic corticosteroid and antihistamine use is recommended for further dosing
- 3. A suggested protocol includes:
  - Oral loratidine 10 mg or IV promethazine 25 mg 30 minutes prior to infusion
  - IV hydrocortisone 100 mg 30 minutes prior to infusion

Ensure hypersensitivity reaction is documented as an allergy/adverse drug reaction as outlined in <u>documentation section</u> above.

# EVALUATION

- RiskMan
- Clinical Audit

#### REVIEW

Review required every 2 years

# **REFERENCES and ASSOCIATED DOCUMENTS**

**Cabrini Policies Procedures and Protocols** 

Patient Allergies and Adverse Drug Reactions Management and Reporting of Anaphylaxis Standing Order-Anaphylaxis – Adrenaline (epinephrine) Auto-Injector Recognising and Responding to Acute Deterioration Resuscitation Plan Patient Consent form Adverse Drug Reaction (Patient information form) Medication Rechallenge (Patient information form) Advanced Care Directives

Prompt Doc No: <#doc_id> Version:	Date Loaded onto Prompt: <#issue_date>	Last Reviewed Date: <#last_review_date>	
<#ver_num>			
Next Review Date: <#next_review_date>	UNCONTROLLED WHEN DOWNLOADED	Page 9 of 10	



#### **Key Legislation and Standards**

Australian Commission on Safety and Quality in Health Care (ACSQHC). (2019). National Safety and Quality Health Service Standards (Second edition): Recognising and Responding to Acute Deterioration.

Australian Commission on Safety and Quality in Health Care (ACSQHC). (2019). National Safety and Quality Health Service Standards (Second edition): Medication Safety

#### References

- 1. Peter MacCullum Cancer Centre (2017) Rechallenge of Anti-cancer Agents Clinical Guideline.
- Castells M.C, Matulonis U.A & Horton T.M (2022) Infusion Reactions to Systemic Chemotherapy. Drews R.E, Adkinson N, Savarese D & Feldweg A (Eds) UpToDate. Available from <u>https://www.uptodate.com/contents/infusion-reactions-to-systemic-chemotherapy#H24</u>
- Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. U.S. Department of Health and Human Services: National Institutes of Health & National Cancer Institute; 2017 <u>https://ctep.cancer.gov/protocoldevelopment/electronic\_applications/docs/CTCAE\_v5\_Quick\_Reference\_8.5x11.pdf</u>
- 4. Laryngopharyngeal dysaesthesia associated with Oxaliplatin [Internet]. eviQ. NSW Government Cancer Institute; 2022 [cited January 2023]. Available from: <u>https://www.eviq.org.au/clinicalresources/side-effect-and-toxicity-management/oropharyngeal/1735-laryngopharyngealdysaesthesia-associated-wit</u>
- 5. DBL Carboplatin<sup>®</sup> (carboplatin). Australian approved product information. Pfizer Pty Ltd [Internet]. Date of TGA approval or last amendment 29/08/22 [cited December 2022] <u>https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-PI-03554-3&d=20221228172310101</u>
- DBL Cisplatin<sup>®</sup> {Cisplatin} Australian approved product information. Pfizer Pty Ltd [Internet].Date of TGA approval or last amendment 27/10/2022. <u>https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-PI-03556-3</u>
- DBL Oxaliplatin<sup>®</sup> (oxaliplatin). Australian approved product information. [Internet]. Pfizer Australia Pty Ltd. Date of TGA approval or last amendment 04/04/2022 [cited December 2022]. <u>https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2018-PI-01867-1&d=20221229172310101</u>

#### **REVISION HISTORY**

Version	Revision date	Revision notes

Executive Sponsor	
Approved By:	Date:
Authorised By:	Date:

Prompt Doc No: <#doc_id> Version:	Date Loaded onto Prompt: <#issue_date>	Last Reviewed Date: <#last_review_date>
<#ver_num>		
Next Review Date: <#next_review_date>	UNCONTROLLED WHEN DOWNLOADED	Page 10 of 10

# Appendix B

\_\_\_\_\_

Nutrition:			Weight on adr	nission:	kg
Have you lost weight since y	our last visit?	No 🗌 Yes	Yes = Comp	lete malnı	utrition screening tool
Malnutrition screening tool (	Complete if asses	ssment is requi	red)		
Question 1: Weight loss		Questic	on 2: Appetite		
Have you lost weight during the without trying? No = 0 points or Unsure = 2 points or Yes = How much weig 0.55.0 = 1 point > 5 - 10kg = 2 points > 10 - 15kg = 3 points > 15kg = 4 points	decreas	u been eating poorly be ed appetite? = 0 points = 1 point	Total combined score of questions 1 and 2: If total score is ≥ 2 refer to Dietetic Services on PAS		
Bladder system assessment Complete only for patients l		CG treatment	Mitmoycin treatr	nant [	N/A – No cancer history
<ol> <li>How would you estimate you last week? Very poor 1 2 3</li> <li>Thinking about the last we How often do you urinate? D</li> </ol>	4 5 6 7 e ek, please answer	general during th excellent r the following c	e <4 Complete	SCST	
3. Have you experienced any			Moderate	Interes	Unbearable
Symptom Burning when urinating	N/A S	Slight	Moderate	Intense	Undearable
Blood in urine					
Unwell / feeling sick					
Fatigue					
Chills					
Pain in joints					
Fever					
Comments:					
Discharge checklist					
Discharge medication provid	ed by Pharmacist	: Yes N	I/A		
Pathology slip pre next treat			I/A		
Patient aware of their next a	•		I/A		
IV cannula removed	PPointinent		I/A		
CVAD- Gripper removed			I/A		
Patient accompanied home	with		·		
- accompanied nome	****		1// \		
Other (Provide details):					
Other (Provide details):					
Other (Provide details):					
Other (Provide details):					
Other (Provide details):					
Other (Provide details):					
Other (Provide details):					
Other (Provide details):					
	Name:		Signatu	re:	Date: D / MM / YYYY
Signature log:	Name: Name:		Signatu Signatu		Date: D/m//

		a Ca
Cabrini	Unit Record Number	alter a
	Surname	t labertail.
_	Unit Record Number Surname Given Names	inete of
Patient Assessment Tool -	Given Names	1 <del>9</del> 1
Infusion Treatment / Day Oncology		Sex
Admission details Introduce self and orientate patient to immedia	Site	
Inform patient / family that questions regarding		
Primary diagnosis:		
Relevant past medical history:		
What treatments are you receiving today?          Cycle:          Dave		
Are you on oral chemotherapy?	, □ No □ Yes	Yes = Provide details
Are you involved in a clinical trial?	No Yes	Yes = Provide details
Are you receiving chemotherapy in the home?	No Yes	Yes = Provide details
Consent		
Acknowledgement of consent to treatment for Blood product consent	m completed No Yes	Yes = Date of consent DD/MM/YY
Documents relating to care		
Do you have any documents relating to your ca	re?	Yes= Enter alert on PAS & file
Advance Care Plan in place	No Yes	documents behind
Medical Power of Attorney	No Yes	medico-legal divider
Other:		
Allergy list		
Medications / anaesthetics: Allergen: React	No Yes	Yes = Complete or verify alert in PAS
Keek		
Solutions & creams e.g. chlorhexidine		Yes = Update Allergy & Adverse
Allergen: React		Drug Reaction & Clinical Alert Divider
 Food e.g. eggs	 □No □Yes	Yes = Updated on Medchart
Allergen: React		
Latex, tapes or other Allergen: React	No Yes	Name:
		Signature:
Reactions to any previous therapy		Yes = Ensure any rechallenge
Have you had a previous reaction to the prescrib		has been approved by the prescriber
	No Yes	No = Contact treating Doctor
Has your Doctor discussed reactions to therapy	and the possible need to rechallenge? No Tyes	
Provide detail:		
Medication list (Ask patient to bring all medica		Pharmacy referral on PAS for:
medication list with subsequent visits)		New patients
Complete medication record for first visit <b>or</b> hav medications since your last admission / treatme		Change of treatment
Yes = Provide details		Requires medication dispensed

\_\_\_\_\_

#### Appendix B

\_\_\_\_\_

Patient symptom and care management diary	
Patient has received diary 🗌 No 🗌 Yes	No = Provide diary to patient
Review diary with patient	N/A (No cancer history)
Encourage patient to document in diary and discuss any concerns	
Risk screening	
Falls: Consider all patients at risk of a fall and implement appropriate risk level	Yes = Consider Allied Health referral
screening strategies Have you had a fall recently or since your last admission	Ensure:
Falls prevention brochure provided (For first visit only)	<ul> <li>Appropriate footwear</li> <li>Provide assistance to bathroom</li> </ul>
Skin: Consider all patients at risk of a pressure injury / skin tear and implement appropriate risk level screening strategies	If present:
Have you had any problems with:	Encourage position change in
Skin tear Pressure injury Rash Abrasion Bruising	bed / chair
Other	Complete RiskMan, take photo(s),
Preventing and management of pressure injury brochure provided (First visit only)	obtain consent and document in Medical Record
Infection:	Yes=
Have you ever been advised that you have a multi-resistant organism?	Complete PAS Alert
CAuris CRE/CPE VRE MRSA ESBL TB Other	Implement appropriate precautions
Details:	<b>Yes</b> to any questions =
Do you currently have any symptoms of vomiting, diarrhoea, fever, cough,	Notify admitting Doctor
sore throat, body aches, runny nose or rash?	Implement appropriate precautions
COVID-19: In the last 14 days have you -	Notify IPC Coordinator
Returned from overseas or been in quarantine?   No   Yes	
Had recent contact with a known or suspected COVID-19 person?	
Had or recently been tested for COVID 19?	
Details of testing and clearance:	
Have you been admitted <b>overnight</b> to any overseas hospital or aged care	Yes and decision to admit
facility in the last 12 months? No Yes	Notify Hospital Coordinator
Details:	Complete PAS Alert
Smoking history	
Are you a current smoker?       No       Yes       Yes = How many per day?         Have you previously smoked?       No       Yes       Yes = When did you quit?	Yes = Quit information provided
Supportive Care Screening Tool (SCST) N/A (No cancer history)	
Has the patient been given the supportive care 'Information about your supportive care	
needs' brochure? No Yes	No = Provide brochure and
The SCST has been completed for:	explanation to the patient
Cycle 1 No Yes	_
Cycle 3 No Yes	No = Ask the patient to complete the SCST
Has there been a change of treatment? No Yes	Yes = Ask the patient to complete the SCST
Distress level last SCST : If > 4 repeat SCST for this visit: score	Distress level > 4 referral actioned
<b>Referral</b> (Consider referral to the following support service)	
Dietitian Physiotherapist Occupational Therapist	Yes = referral on PAS
Social Worker Breast Care nurse Neuro Oncology nurse	— = Chronic illness plan discussed
Palliative Care Pastoral Services	with patient
Other:	
Eastern Cooperative Oncology Group (ECOG) status	
ECOG grade = (Refer to laminated matrix)	
Diabetes	
Are you a diabetic? No Yes	Yes to either = Undertake BSL &
If yes: Type 1 Type 2	Record level:
Diet Tablets Insulin	
Non diabetic patient, BSL required?	

Assessments	Grading				Comment & action	
	Nil	Grade1*	Grade2	Grade 3 and 4	Grade 1 (Green) – proceed wi Grade 2 (Amber) – senior n	
	reported	(Green-)	(Amber)	(Red)	Grade 3 & 4 (Red) – medical	
Fatigue						
Pain						
Temperature – fever						
Temperature – low body temp						
Mucositis						
Appetite						
Nausea						
Vomiting						
Constipation						
Diarrhoea						
Peripheral neuropathy						
Respiratory (E.g. SOB, cough,						
wheeze)						
Urinary (E.g. frequency, burning						
on micturition ) Tinnitus						
Dedema						
Other: IV / CVAD access						
V / CVAD education: ר No אס און No אס און No אס און No אין און No אין	′es 🗌 Not r	equired			isk associated with CVAD disc ine care and complication man	
Peripheral cannulation record:	1					
Attempt number Ca	innulation t	уре	Cannula	ation site	Special preparation	Name / signature
Central Venous Access Device o						
Date of insertion: DD/MM/ YMA		on site: Rig	ht / left		m External PICC length	cm
	-	-		C		cm
CVAD type: CVC Port []		edle lengt		]	cm	
PICC / PORT (Record each visit)						
Patency blood return: No No						
Line flushed:		ished with	:			
Cap changed:						
Dressing changed:		vpe of dres	sing applie	ed:		
Dressing change next due: DD/M	M/YYYY					
Entry site: Clean & dry Ir		_				
Action: Accessed by:						
			Signature			Date: DD / MA
Name:	_		Signature:			Date: DD/MM/MMY

1.\*Common Terminology Criteria for Adverse Events (CTCAE) V4 June 20102 2. Cabrini, Patient symptom and care management diary – Treatment

\_\_\_\_

2 of 4