Policy for the use of Intravenous Ganciclovir
<table>
<thead>
<tr>
<th>Policy Title:</th>
<th>Policy for the use of intravenous Ganciclovir</th>
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</thead>
<tbody>
<tr>
<td><strong>Purpose &amp; Background</strong></td>
<td>IV Ganciclovir is a drug that is rarely given but requires specialist knowledge to administer safely. The Chemotherapy nurses at East Cheshire Trust will provide this service if a patient requires IV Ganciclovir.</td>
</tr>
</tbody>
</table>
| **Scope** | This policy applies to the following staff groups who will treat patients with CMV  
- Consultants  
- Chemotherapy specialist nurses  
- Pharmacy Teams  
- Ward Nurses (acute) |
| **Policy Area:** | Cancer services |
| **Version Number:** | 1 |
| **Issued By:** | Pharmacy |
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| **Document Reference:** | ECT002785 |
| **Contributing Authors:** | Lead cancer Nurse  
Deputy Chief Pharmacist |
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June 2017 |
## Contents

1. Objectives ........................................ page.....5
2. Target Audience ................................... page.....5
3. Service Objectives: ............................... page.....5
4. Scope ............................................. page.....5
5. Introduction ....................................... page.....5
6. Responsibilities ..................................... page.....6
7. Patient Consent and precautions for use .............. page .....6
8. Obtaining ganciclovir in hours ....................... page ......7
9. Obtaining ganciclovir out of hours ................. page .....8
10. Administration ...................................... page.....8
11. Disposal of IV Ganciclovir ......................... page.....8
1. Objectives

East Cheshire NHS Trust is committed to providing optimum quality of care across all areas; this extends to patients who require the administration of IV Ganciclovir. This policy aims to equip the practitioners with the appropriate underpinning theoretical knowledge to confidently deliver seamless and effective care to patients within a supportive and evidence based framework.

2. Target Audience

The target audience of this policy extends across secondary care areas. This document provides a management framework for teams to be able to manage administration of IV Ganciclovir.

3. Service Objectives:

- To ensure the availability of Ganciclovir via pharmacy
- To promote safe and standardised practice to patients receiving IV Ganciclovir.
- To ensure the safety of practitioners administering IV Ganciclovir

4. Scope

This SOP applies to the following staff groups who treat patients with Cytomegalovirus (CMV) infections.

- Service Managers
- Specialist Nurses and Specialist Nurse Teams
- Consultants
- Junior Doctors
- Pharmacy Teams
- Ward Nurses (acute)

5. Introduction

Ganciclovir is indicated for the treatment of life-threatening or sight-threatening Cytomegalovirus (CMV) infections in immunocompromised individuals. It may also be used for the prevention of CMV disease, specifically in those patients receiving immunosuppressive therapy secondary to organ transplantation.

CMV is often acquired in childhood and is endemic in the population. The likelihood of infection varies among different groups in the population but overall in the UK approximately half of all adults have been infected with CMV. The symptoms of CMV infections are similar to the common cold and treatment is very rarely indicated, unless the patient is immunocompromised. Since ganciclovir is considered a potential teratogen and carcinogen in humans, caution should be exercised in its handling. If clinically indicated, ganciclovir should be supplied by pharmacy and arrangements made for administration by either a chemotherapy nurse or member of nursing staff who has been trained and designated competent.

This policy was developed to:

- Enable patients to safely receive intravenous Ganciclovir at East Cheshire Trust
- Ensure safe and consistent practice
- Ensure the safety of staff ensuring those administering this drug have been trained in its administration
6. Responsibilities

**Associate Directors, Clinical Directors and Service Managers** are responsible for ensuring the services they manage are aware of all Standard Operating Procedures for the administration of IV Ganciclovir

**Ward Managers** are responsible for ensuring the relevant specifications outlined in these SOP are adhered to in practice and all new starters are made aware of their existence on the internet site where the most up to date version will be available.

**Registered Nurses** All professionals are personally and professionally accountable for their actions and omissions in their practice and must always be able to justify their decisions and ensure compliance to ECH operating procedures/policies and NMC Standards for Medicines Management.

**Medical Staff**
These clinicians will accept overall clinical responsibility for the patients they prescribe this medication for. They are responsible for ensuring the patient is fully aware of all the side effects and consent has been taken.

**Pharmacy service managers** are responsible for ensuring the relevant specifications outlined in these SOP are adhered to in practice and all new starters are made aware of their existence on the internet site where the most up to date version will be available.

**Relevant trust policies to use in conjunction with this guidance**

- ECT Hand washing policy
- ECT The use of personal protection equipment
- ECT Extravasation policy
- ECT Infusion Devices policy
- ECT Administration and Disposal of Medicines Policy
- ECT Waste management Policy

7. Patient Consent and precautions for use

Prior to initiation of ganciclovir treatment, patients should be advised of the potential risks by the consultant with clinical responsibility for the patient. This should be documented in the medical notes.

In animal studies ganciclovir was found to be mutagenic, teratogenic, aspermatogenic, carcinogenic and to impair fertility. Ganciclovir may cause temporary or permanent inhibition of spermatogenesis.

Ganciclovir should therefore be considered a potential teratogen and carcinogen in humans with the potential to cause birth defects and cancers. Therefore, women of child bearing potential must be advised to use effective contraception during treatment and for at least 30 days thereafter. Men must be advised to practice barrier contraception during treatment, and for at least 90 days thereafter, unless it is certain that the female partner is not at risk of pregnancy.

The use of ganciclovir warrants extreme caution, especially in the paediatric population due to the potential for long-term carcinogenicity and reproductive toxicity. The benefits of treatment should be carefully considered in each case and should clearly outweigh the risks.

**IV Ganciclovir is a vesicant and should be administered through a PICC line.** If the insertion of a PICC line is not available immediately this should be inserted as soon as possible. The drug is an
irritant; it is alkaline and may cause phlebitis. It may be given peripherally although care must be taken to ensure the IV cannula is functioning well before use. The following precautions should be taken:

- Monitor patient and entry site throughout the infusion
- Check for pain on infusion, can cause phlebitis.
- Extravasation can cause tissue damage – seek urgent expert advice on management if this occurs. Refer to the current Extravasation policy.
- Extravasation category is “Blue” so treatment is with cold compress to the area and topical hydrocortisone 1% cream if required.
- Skin contact: Wash thoroughly with soap and water.
- Eye contact: Irrigate with copious amounts of water.

Ganciclovir should be used with caution in patients with reduced renal function. Dose adjustment is required, contact pharmacy for advice on dose adjustment.

Ganciclovir treatment commonly results in cytopenias and extreme caution should be applied using it in patients with impaired bone marrow function (neutrophils < 1x10^9/l or platelets < 50x10^9/l)

For patients with severe bone marrow depression (neutrophils < 0.5x10^9/l or platelets < 25x10^9/l), manufacturers contraindicate its use. In this rare situation, if options are very limited, the drug use needs to be approved by both consultant responsible for patient care and the microbiology consultant.

Please note Ganciclovir should not be administered to patients with an allergy to aciclovir or valaciclovir

8. Obtaining ganciclovir in hours

If clinically indicated and appropriate and a request is made by the ward pharmacist to Pharmacy Aseptic Unit from **Monday to Friday 8:45am to 4:00pm**, doses of aseptically prepared ready to administer bag can be provided. Please see the following steps of how a ward pharmacist should arrange supply from Aseptic Unit:

1. Medical staff on the ward discuss with the ward pharmacist about commencing a patient on ganciclovir (Consultant Microbiologist should be involved)
2. If clinically indicated, the ward pharmacist should advise Pharmacy Aseptics at the earliest opportunity to ensure treatment and preparation materials are available.
3. The Medical staff should write a valid prescription for IV ganciclovir in the appropriate section of the drug chart.
4. The ward pharmacist should communicate with ward staff about the handling precaution of ganciclovir. For example, pregnant women or women of child bearing potential should not handle this product. **Ward need to be informed that this drug can only be given by a trained Chemotherapy nurse or member of nursing staff who has been trained and designated competent.**
5. The ward nursing staff should contact the cancer resource centre on x3198 to advise that administration of ganciclovir will be required and at what time.
6. The drug chart which has been clinically checked, verified and signed by the ward pharmacist should be sent to Pharmacy Aseptics as soon as possible, so that aseptic preparation can be commenced.
7. A photocopy of the IV ganciclovir prescription will be retained in Pharmacy Aseptics and the original copy can be sent back to the ward.

8. A disposal and handling kit would also be provided along with the aseptically prepared IV ganciclovir infusion bag. (See appendix 1)

9. **Obtaining ganciclovir out of hours**

If clinically indicated and appropriate, ganciclovir will need to be sourced via the pharmacy weekend, bank holiday or on-call service.

Medical staff on the ward should discuss with the on-call pharmacist about commencing a patient on ganciclovir (the microbiology consultant on-call should be involved). The on-call pharmacist should discuss all aspects of clinical appropriateness including the choice of antiviral, allergy status, patient’s medical condition and medication history.

If IV ganciclovir treatment is deemed to be necessary, the site manager should check the availability of a chemotherapy nurse to administer the drug (a list of contact details will be held with switchboard).

Once the availability of a chemotherapy nurse has been confirmed, the on-call pharmacist will contact a local hospital to source a supply of a ready made bag of ganciclovir. There is a local agreement with Central Manchester NHS Foundation Trust so they should be contacted first, should they be unable to supply then other local hospitals should be contacted starting with the closest.

Once a supply has been confirmed the on-call pharmacist should advise the site manager where the ganciclovir is coming from and when it should arrive and they should then liaise with the chemotherapy nurse. The ward nurse should be advised to obtain a handling and disposal kit (Appendix 1) which is kept in emergency reserve cupboard.

**Contacting the Chemotherapy Nurses out of hours**

This must be done via the site manager (a list of contact details will be held with switchboard)

10. **Administration**

- Wear PPE: An apron and nitrile gloves should be worn.
- Prime the giving line with 0.9% sodium chloride.
- Attach the Ganciclovir bag to the line working at waist height (not exposing the eyes).
- Infuse over at least 60 minutes.
- When the infusion is finished, the line should be flushed again with 0.9% sodium chloride.
- Ganciclovir should **not** be mixed with other IV products.
- Hands should be washed afterwards in case of inadvertent contact with ganciclovir.

11. **Disposal of IV Ganciclovir**
Content of Kit:
- A pack of gloves
- A pack of aprons
- Cytotoxic Bin with a purple lid and tag

Instruction of disposal:
Please dispose of used items as follows:
Used Ganciclovir infusion bags – In purple lidded Cytotoxic Bin
Any materials used for administration e.g. needles – In purple lidded Cytotoxic Bin
Aprons, Gloves, Masks, etc. – In purple lidded Cytotoxic Bins

Once Bin is filled, shut lid to final closure Mark. Tag the bin and stock the cytotoxic sticker over the lid. Dispose according to ward practice

Appendix 1. Safety checklist prior to treatment with Ganciclovir

☐ Patient must be fully informed of the risks of treatment
- Patient must have appropriate venous access (see section 7)

- Ganciclovir must be administered by a chemotherapy nurse (the availability of this should be confirmed prior to sourcing the product out of hours)

- Ganciclovir must not be reconstituted in a ward environment

- Spillage of ganciclovir should be managed according to the cytotoxic spillage and contamination policy

- Handling and disposal should be undertaken by the chemotherapy nurse according to the administration and disposal of medicines policy and local cytotoxic spillage SOPs

Equality Analysis (Impact assessment)

1. What is being assessed?
Policy for the use of Intravenous Ganciclovir

Details of person responsible for completing the assessment:
- Name: Karen Adams
- Position: Deputy Chief Pharmacist
- Team/service: Pharmacy

State main purpose or aim of the policy, procedure, proposal, strategy or service:
This policy provides guidance relating to procurement, prescribing, preparation and administration of Intravenous Ganciclovir at ECNT

2. Consideration of Data and Research
To carry out the equality analysis you will need to consider information about the people who use the service and the staff that provide it.

2.1 Give details of RELEVANT information available that gives you an understanding of who will be affected by this document

Cheshire East (CE) covers Eastern Cheshire CCG and South Cheshire CCG. Cheshire West & Chester (CWAC) covers Vale Royal CCG and Cheshire West CCG. In 2011, 370,100 people resided in CE and 329,608 people resided in CWAC.

Age: East Cheshire and South Cheshire CCG’s serve a predominantly older population than the national average, with 19.3% aged over 65 (71,400 people) and 2.6% aged over 85 (9,700 people).

Vale Royal CCGs registered population in general has a younger age profile compared to the CWAC average, with 14% aged over 65 (14,561 people) and 2% aged over 85 (2,111 people).

Since the 2001 census the number of over 65s has increased by 26% compared with 20% nationally. The number of over 85s has increased by 35% compared with 24% nationally.

Race:
- In 2011, 93.6% of CE residents, and 94.7% of CWAC residents were White British
- 5.1% of CE residents, and 4.9% of CWAC residents were born outside the UK – Poland and India being the most common
- 3% of CE households have members for whom English is not the main language (11,103 people) and 1.2% of CWAC households have no people for whom English is their main language.

Gender: In 2011, c. 49% of the population in both CE and CWAC were male and 51% female. For CE, the assumption from national figures is that 20 per 100,000 are likely to be transgender and for CWAC 1,500 transgender people will be living in the CWAC area.

Disability:
- In 2011, 7.9% of the population in CE and 8.7% in CWAC had a long term health problem or disability
- In CE, there are c.4500 people aged 65+ with dementia, and c.1430 aged 65+ with dementia in CWAC. 1 in 20 people over 65 has a form of dementia
- Over 10 million (c. 1 in 6) people in the UK have a degree of hearing impairment or deafness.
- C. 2 million people in the UK have visual impairment, of these around 365,000 are registered as blind or partially sighted.
- In CE, it is estimated that around 7000 people have learning disabilities and 6500 people in CWAC.
- Mental health – 1 in 4 will have mental health problems at some time in their lives.

**Sexual Orientation:**
- CE - In 2011, the lesbian, gay, bisexual and transgender (LGBT) population in CE was estimated at 18,700, based on assumptions that 5-7% of the population are likely to be lesbian, gay or bisexual and 20 per 100,000 are likely to be transgender (The Lesbian & Gay Foundation).
- CWAC - In 2011, the LGBT population in CWAC is unknown, but in 2010 there were c. 20,000 LGB people in the area and as many as 1,500 transgender people residing in CWAC.

**Religion/Belief:**
The proportion of CE people classing themselves as Christian has fallen from 80.3% in 2001 to 68.9% in 2011 and in CWAC a similar picture from 80.7% to 70.1%, the proportion saying they had no religion doubled in both areas from around 11%-22%.

- **Christian:** 68.9% of Cheshire East and 70.1% of Cheshire West & Chester
- **Sikh:** 0.07% of Cheshire East and 0.1% of Cheshire West & Chester
- **Buddhist:** 0.24% of Cheshire East and 0.2% of Cheshire West & Chester
- **Hindu:** 0.36% of Cheshire East and 0.2% of Cheshire West & Chester
- **Jewish:** 0.16% of Cheshire East and 0.1% of Cheshire West & Chester
- **Muslim:** 0.66% of Cheshire East and 0.5% of Cheshire West & Chester
- **Other:** 0.29% of Cheshire East and 0.3% of Cheshire West & Chester
- **None:** 22.69% of Cheshire East and 22.0% of Cheshire West & Chester
- **Not stated:** 6.66% of Cheshire East and 6.5% of Cheshire West & Chester

**Carers:** In 2011, nearly 11% (40,000) of the population in CE are unpaid carers and just over 11% (37,000) of the population in CWAC.

**2.2 Evidence of complaints on grounds of discrimination:** (Are there any complaints or concerns raised either from patients or staff (grievance) relating to the policy, procedure, proposal, strategy or service or its effects on different groups?)

No

**2.3 Does the information gathered from 2.1 – 2.3 indicate any negative impact as a result of this document?**

No

**3. Assessment of Impact**

Now that you have looked at the purpose, etc. of the policy, procedure, proposal, strategy or service (part 1) and looked at the data and research you have (part 2), this section asks you to assess the impact of the policy, procedure, proposal, strategy or service on each of the strands listed below.

**RACE:**

From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, racial groups differently? Yes ☐ No ✗
Explain your response: Applies to all patients within the scope of the policy following completion of the relevant assessments. Where a person’s first language is not English, staff will follow the Trust’s interpretation and translation policy.

GENDER (INCLUDING TRANSGENDER):
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, different gender groups differently? Yes ☐ No x

Explain your response: Applies to all patients within the scope of the policy following completion of the relevant assessments. The Trust has a transgender policy and staff will be mindful of this along with any contraindications with the maintenance drugs patients may be taking on a long term basis. Included in the policy is information relating to reproduction - In animal studies ganciclovir was found to be mutagenic, teratogenic, aspermatogenic, carcinogenic and to impair fertility. Ganciclovir may cause temporary or permanent inhibition of spermatogenesis.

Ganciclovir should therefore be considered a potential teratogen and carcinogen in humans with the potential to cause birth defects and cancers. Therefore, women of child bearing potential must be advised to use effective contraception during treatment and for at least 30 days thereafter. Men must be advised to practice barrier contraception during treatment, and for at least 90 days thereafter, unless it is certain that the female partner is not at risk of pregnancy.

DISABILITY:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, disabled people differently? Yes ☐ No x

Explain your response: Applies to all patients within the scope of the policy following completion of the relevant assessments. Use of an interpreter may be employed where necessary for Deaf patients or deaf blind. Information can be provided in a variety of formats such as large print, audio, Braille and easy read. For patients with learning disabilities, picture communication books are available in ward communication boxes and staff have access to learning disabilities and autism awareness training.

AGE:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, age groups differently? Yes ☐ No x

Explain your response: Applies to all patients within the scope of the policy following completion of the relevant assessments. The use of ganciclovir warrants extreme caution, especially in the paediatric population due to the potential for long-term carcinogenicity and reproductive toxicity. The benefits of treatment should be carefully considered in each case and should clearly outweigh the risks. This information is included in the policy.

LESBIAN, GAY, BISEXUAL:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, lesbian, gay or bisexual groups differently? Yes ☐ No x

Explain your response: Applies to all patients within the scope of the policy following completion of the relevant assessments.
RELIGION/BELIEF:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, religious belief groups differently? Yes ☐ No ☒

Explain your response: Applies to all patients within the scope of the policy following completion of the relevant assessments.

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CARERS:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, carers differently? Yes ☐ No ☒

Explain your response: Patient consent would be sought unless life threatening situation.

__________________________

OTHER: EG Pregnant women, people in civil partnerships, human rights issues.
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect any other groups differently? Yes ☐ No ☒

Explain your response: Applies to all patients within the scope of the policy following completion of the relevant assessments.

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4. Safeguarding Assessment - CHILDREN

<table>
<thead>
<tr>
<th>a. Is there a direct or indirect impact upon children?</th>
<th>Yes ☒ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people:</td>
<td></td>
</tr>
<tr>
<td>Applies to all paediatric patients within the scope of the policy following completion of the relevant assessments – see section on age also.</td>
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<tr>
<td>c. If no please describe why there is considered to be no impact / significant impact on children.</td>
<td></td>
</tr>
</tbody>
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5. Relevant consultation
Having identified key groups, how have you consulted with them to find out their views and that the policy, procedure, proposal, strategy or service will affect them in the way that you intend? Have you spoken to staff groups, charities, national organisations etc?

Policy applies to all patient groups equally.

__________________________

6. Date completed: 13/06/17 Review Date: June 2019

7. Any actions identified: Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?

<table>
<thead>
<tr>
<th>Action</th>
<th>Lead</th>
<th>Date to be Achieved</th>
</tr>
</thead>
</table>
8. Approval – At this point, you should forward the template to the Trust Equality and Diversity Lead lynbailey@nhs.net

Approved by Trust Equality and Diversity Lead: 

Date: 15.6.17