NHS Greater Glasgow and Clyde

Community Pharmacy

Community Pharmacy Provision of Anti-Retrovirals - Service Specification

1. Service Aim

1.1. To facilitate access to the effective treatment for HIV by utilising the community pharmacy network

1.1.1. Working in partnership with the Specialist Pharmacy Team (SPT) in secondary care.

1.1.2. Dispensing Anti-Retrovirals (ARVs) as prescribed according to need.

1.1.3. Ensuring each supervised dose is consumed in accordance with the appropriate standard operating procedure.

1.1.4. Monitoring the patient's adherence to prescribed treatment.

1.1.5. Providing general health advice including pharmaceutical public health services, and signposting to facilitate access to further advice or assistance.

1.1.6. Promoting patient safety and appropriate harm minimisation strategies for patients with a history of illicit drug use.

2. Service Outline & Standards

2.1. The community pharmacy contractor will ensure that the pharmacist and pharmacy staff offer a friendly, non-judgemental, patient-centred and confidential service.

2.2. The service should be operated from premises providing a level of confidentiality and privacy which is acceptable to the patient.

2.3. The community pharmacy will develop and maintain a close working relationship with the prescriber and the SPT within Brownlee Centre, Gartnavel General Hospital. This should include a process which will allow both information sharing where required, and the sharing of any medicine changes.

2.4. The dispensing and supervision procedure should follow the relevant procedures.

2.5. The community pharmacist will ensure that appropriate patient medication records are maintained.

2.6. Pharmacy staff should be able to provide information, advice and signposting when required, on a range of related health and addiction issues including how to access local treatment services.

2.7. In line with GPhC standard 2.1, the responsible pharmacist must ensure that there is sufficient staffing, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided.

The pharmacist must ensure compliance with GPhC standard 1.8, namely that children and vulnerable adults are safeguarded.

3. Training

3.1. It is necessary that the pharmacists involved in the provision of the service ensure an up-to-date knowledge of Anti-retroviral medicines, treatment regimes and any potential side effects and undertake the relevant NES webinar - HIV medicines.

3.2. The community pharmacist and staff should participate in local training initiatives and peer review sessions identified by NHS GGC.

4. Monitoring and evaluation

4.1. It is a requirement of the service that appropriate records are kept and maintained by the community pharmacy contractor. This will enable verification of service provision and provide information to the Health Board for internal and external audit, evaluation and monitoring purposes.

4.2. The pharmacy will participate in local audit and service evaluation to locally agreed levels.

5. Payment

5.1. A fee will be paid as per local agreement in line with the service specifications.

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Information for Community Pharmacists

- Patients should avoid missing any dose. **It is essential that the Brownlee SPT are contacted on 0141 211 3383 if a patient misses 2 consecutive doses or 5 doses per month; *do not withhold a dose.***

- If a patient appears '**under the influence**' the ARV dose **should not** be withheld. Co-prescribed opioid replacement therapy may need to be withheld but this does not impact on ARV treatment.

- If a patient mistakenly consumes two doses of any ARV, advise them to drink plenty water and report this back to the SPT.

- Possible interactions with opioid replacement therapy and ARVs will have been considered before the patient is commenced on treatment and transferred through to community pharmacy. Any new medications commenced must be checked through the Brownlee SPT or at

  www.hiv-druginterations.org

- All patients should be counselled by the specialist team on what to expect when commencing or changing ARVs. Mild side-effects are expected at the outset of treatment but these should settle after approximately one week.
  For mild symptoms, it is safe for patients to use paracetamol, cetirizine or loperamide.

- Triumeq® is recommended to be administered 2 hours before or 6 hours after taking any antacids, calcium iron supplements, multivitamins or ensure drinks.

- Any severe side-effects such as vomiting, rash, abdominal pain and muscle aches should be reported back to the SPT.

- Vomiting within an hour of taking the tablet is likely to reduce absorption. It is therefore advisable to attempt to take a second dose.

- Vomiting regularly – report back to SPT.

Hypersensitivity Reactions

If a patient is prescribed Abacavir there is always the possibility of a hypersensitivity reaction.

The patient should be given an alert card to carry - ensure they have this.

If you or the patient suspects any adverse reaction which may indicate a hypersensitivity reaction this must be reposted immediately to the specialist team (0141 211 3383) or NHS 24 on 111 out with working hours.

Further details on all prescribed ARV's is shown below

Advice to be supplied to the patient.

Once started, do not stop any ARVs without first contacting Brownlee specialist medical/pharmacy team 0141 211 3383 (Mon-Fri 9am-5pm).

A dose should never be doubled.

Ensure **the patient** knows:

- What dose of medication to take?
- When to take?
- Is it supervised or not?
- What to do if a dose is missed?
- **Report 2 consecutive missed days or 5 missed days over a month to the Brownlee team**.

Advise the patient to always check with their GP and/or pharmacist that any new medicine, including OTC medicine, herbal medicines or illicit/recreational drugs are safe to take with treatment regimen.

www.hiv-druginteractions.org

Check the patients understanding of the side effects of the medicines.

Refer a patient with serious side effects or who is concerned about ARV side effects or treatment to the SPT or NHS 24 on 111 outside clinic hours.

Encourage patients to come at the same time each day, to try and ensure drug levels don't drop out with therapeutic range.

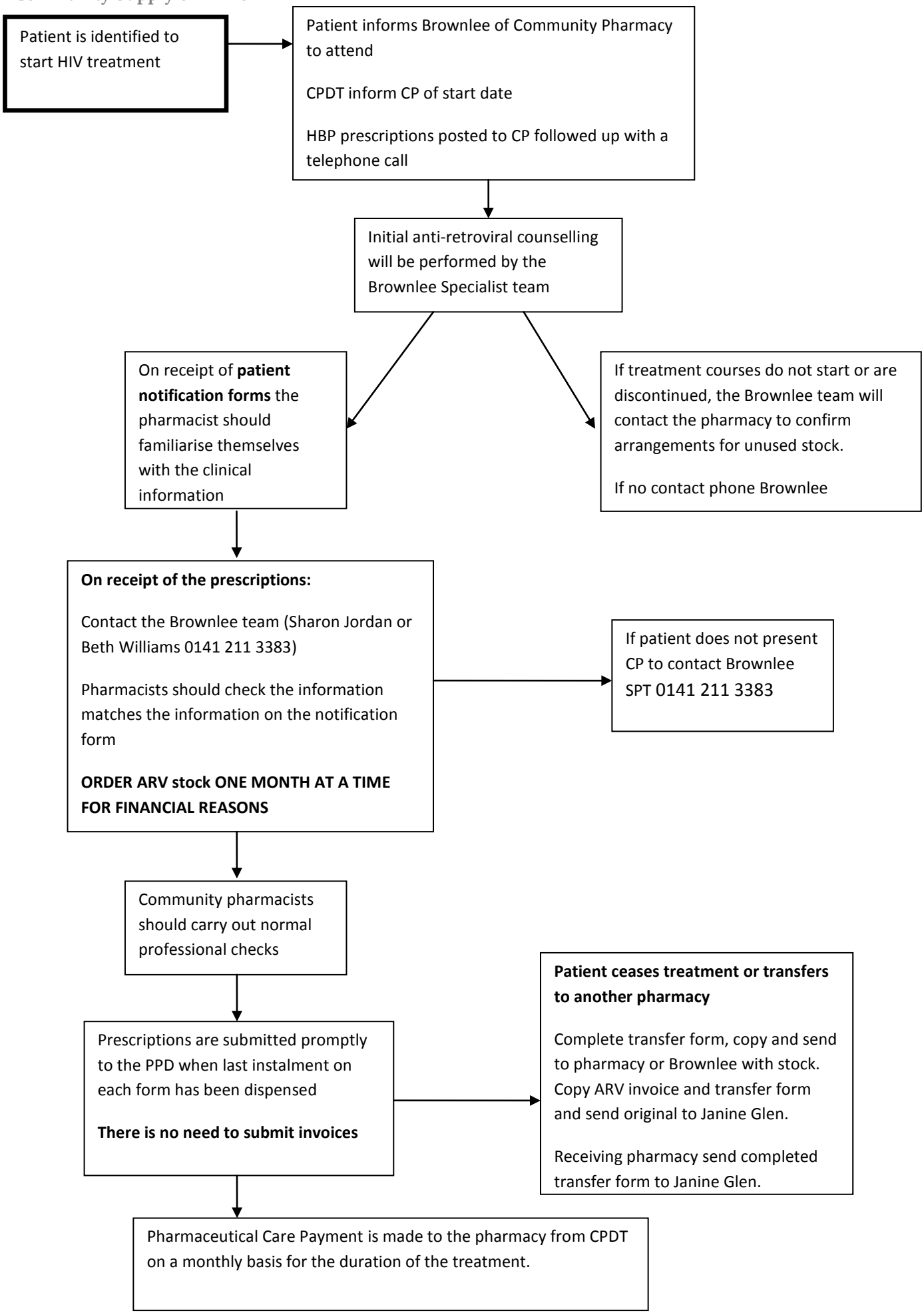
Questions to consider with the patient

- Is the patient taking their medicine(s) as prescribed?
  Yes ☐ No ☐

- Does the patient know what to do if they miss a dose?
  Yes ☐ No ☐

- Is the patient aware to make the Brownlee/community pharmacist aware of any new medicines initiated during treatment course?
  Yes ☐ No ☐

- Is the patient aware of common side effects of their medications?
  Yes ☐ No ☐


Patient is identified to start HIV treatment
Patient informs Brownlee of Community Pharmacy to attend
CPDT inform CP of start date
HBP prescriptions posted to CP followed up with a telephone call
Initial anti-retroviral counselling will be performed by the Brownlee Specialist team
On receipt of patient notification forms the pharmacist should familiarise themselves with the clinical information
If treatment courses do not start or are discontinued, the Brownlee team will contact the pharmacy to confirm arrangements for unused stock.
If no contact phone Brownlee
On receipt of the prescriptions:
Contact the Brownlee team (Sharon Jordan or Beth Williams 0141 211 3383)
Pharmacists should check the information matches the information on the notification form
ORDER ARV stock ONE MONTH AT A TIME FOR FINANCIAL REASONS
If patient does not present CP to contact Brownlee SPT 0141 211 3383
Community pharmacists should carry out normal professional checks
Prescriptions are submitted promptly to the PPD when last instalment on each form has been dispensed
There is no need to submit invoices
Patient ceases treatment or transfers to another pharmacy
Complete transfer form, copy and send to pharmacy or Brownlee with stock. Copy ARV invoice and transfer form and send original to Janine Glen.
Receiving pharmacy send completed transfer form to Janine Glen.
Pharmaceutical Care Payment is made to the pharmacy from CPDT on a monthly basis for the duration of the treatment.

ABACAVIR (ZIAGEN®)

Each tablet contains 300mg of Abacavir.

Each tablet is scored; yellow in colour, biconvex, capsule shaped and engraved with 'GX 623' on both sides, and can be divided into equal halves.

How to take?

The recommend dose of Abacavir is 600mg daily. This may be either one tablet (300mg) twice daily or two tablets (600mg) once daily.

Abacavir can be taken with or without food and should not be crushed.

Missed dose

If a dose is missed take the next dose as planned, do not double the dose.

Hypersensitivity reactions

Abacavir can cause a serious hypersensitivity reaction. This hypersensitivity reaction is linked to the presence of the gene HLA-B*5701 for which the patient will have been tested prior to being prescribed Abacavir.

Hypersensitivity reactions observed for each ARV share some common features such as fever and/or rash, with other symptoms indicating multi-organ involvement.

Symptoms usually appear within the first six weeks (time to onset was typically 10-14 days) following initiation of treatment of Abacavir, although reactions may occur at any time during therapy.

Presentation with a **RASH** and **one of the following symptoms MUST be reported** to the Brownlee specialist team:

- FEVER
- FEELING UNWELL OR EXTREMLEY TIRED
- MUSCLE AND JOINT PAIN
- BLISTERING OF THE SKIN
- CONJUNCTIVITIS
- MOUTH ULCERS
- SWELLING OF THE EYES, MOUTH, THROAT OR FACE
- YELLOWING OF THE SKIN OR EYES
- DARK URINE
- PALE STOOLS

Patients are given an 'alert card' to carry on their person

Interactions

Abacavir concentrations may be reduced by **Rifampacin**, **Phenytoin** and **Phenobarbital**. Do not withhold these medicines if a patient presents with a prescription. During working hours contact SPT to discuss otherwise, dispense to patient and contact SPT at next available time.

Co-administration of Abacavir and Ribavirin will potentially reduce Ribavirin effectiveness; this will be considered by the SPT.

Darunavir (e.g. Prezista® & Rezolsta®)

Darunavir is available as different formulations and in a variety of strengths. A number of factors determine the dose and frequency of administration. In adults the most common dose of Darunavir is 800mg once daily or 600mg twice daily co-administered at the same time as a boosting agent (either ritonavir or cobicistat).

Rezolsta® is a fixed dose combination product of darunavir plus cobicistat.

How to take?

Darunavir, must always be given orally with a boosting agent (either ritonavir or cobicistat) in combination with other antiretroviral medicines. Darunavir is also available as an oral suspension for those who are unable to swallow darunavir tablets.

Patients should be instructed to take darunavir, irrespective of which preparation, with food as this enhances absorption.

Missed doses

Advice is dependent on formulation, dose and frequency of administration.

Interactions

The protease inhibitors are highly prone to pharmacokinetic drug interactions because of their propensity to alter the activity of several metabolic enzymes and drug transporters.

For example, darunavir, ritonavir and cobicistat are inhibitors of CYP3A, CYP2D6 and P-gp but darunavir/ritonavir is also known to induce activity of CYP2C9.

Please check for interactions using www.hiv-druginteractions.org for any new medicine, OTC product or herbal remedy. Refer back to clinical pharmacy team if information unavailable or if interpretation required. Co-administration with medicinal products metabolised by CYP3A may result in increased plasma concentrations of the other medicines which could increase and/or prolong their therapeutic and adverse effects.

Contraindicated medications include: alfuzosin, disopyramide, flecainide, amiodarone, quinidine, clarithromycin, apixaban, dibigatran, rivaroxaban, phenobarbital, phenytoin, rifampicin, rifapentine, ticagreglor, quetiapine, midazolam, St John's Wort. This list is not exhaustive.

Driving

There is no negligible influence on the ability to drive or use machines. However dizziness has been reported in some patients.

Adverse Effects

Common side effects include headache, dizziness, vomiting, nausea, abdominal pain, rash (including macular, macularopapular, popular, erythematous and prurtic rash), pruritus, asthenia and fatigue. Any new rash, especially on commencing Darunavir, should be referred back to the clinical team. This list is not exhaustive.

DOLUTEGRAVIR (TIVICAY®)

Adults 40kg and above will take a 50mg tablet.

Each tablet is yellow, round, biconvex, approximately 9 mm in diameter debossed with 'SV 572' on one side and '50' on the other side.

How to take?

One tablet once daily (may be twice daily when co-administered with e.g. efavirenz, nevirapine, rifampicin of if there is resistance).

Dolutegravir can be taken with or without food.

Missed doses

If the patient misses a dose of dolutegravir, they should take the dose as soon as possible, providing the next dose is not due within 4 hours. If the next dose is due within 4 hours, the patient should not take the missed dose and simply resume the usual dosing schedule.

Interactions

- Dose adjustments are recommended when co-administered with **Carbamazepine, Oxcarbazepine, Phenytoin, Phenobarbital**.
- Dolutegravir is contraindicated with **St John's Wort**.
- Dose adjustments of **metformin** should be considered when co-administered.
- Dolutegravir is decreased in the presence of antacids and calcium or iron supplements.

Dolutegravir is recommended to be administered 2 hours before or 6 hours after taking any antacids, calcium or iron supplements.

Driving

Patients should be informed that dizziness has been reported during treatment with dolutegravir. The clinical status of the patient and the adverse reaction profile of dolutegravir should be borne in mind when considering the patient's ability to drive or operate machinery.

Hypersensitivity reactions

One hypersensitivity reaction has been reported with Dolutegravir, and was characterised by rash accompanied by general malaise, fever, fatigue, muscle or join aches. Dolutegravir should not be discontinued if signs or symptoms of hypersensitivity appear – contact SPT immediately.

Adverse Reactions

The most commonly seen adverse reactions were diarrhoea (18%), nausea (13%) and headache (13%).

GENVOYA®

Genvoya is a fixed-dose combination medicine used for the treatment of HIV infection, consisting of:

1. Elvitegravir 150mg
2. Cobicistat 150mg
3. Emtricitabine 200mg
4. Tenofovir alafenamide equivalent to tenofovir alafenamide 10mg

Genvoya® is a capsule shaped, film-coated tablet, debossed with "GSI" on one side and "501" on the other.

How to take Genvoya®?

One tablet is to be taken once daily with food.

Missed dose

If the patient misses a dose within 18 hours of the time it is usually taken, the dose should be taken with food as soon as possible and resume the normal schedule. If a patient misses a dose by more than 18 hours, the patient should not take the missed dose and simply resume the usual dosing schedule.

If the patient vomits within 1 hour of taking Genvoya® another tablet should be taken.

Interactions

Co-administration with the following medicines may cause adverse reactions:

- **Alfuzoin, amiodarone, quinidine, rifampicin, dihydroergotamine, ergometrine, ergotamine, cisapride, St John's Wort, lovastatin, simvastatin, pimozide, midazolam, triazolam, sildenafil** for the treatment of pulmonary arterial hypertension.

Adverse Reactions

Patients may present with adverse reactions: nausea, fatigue, rash, diarrhoea, vomiting, abdominal pain, flatulence, headache, dizziness, abnormal dreams, dyspepsia, depression, anaemia, angioedema and puritus.

LAMIVUDINE (EPIVIR®)

There are two different Epivir® tablet strengths available:

The 150mg strength is a film coated, white, diamond shaped scored tablet with “GX CJ7” on both faces.

The 300mg tablet is film coated, grey, diamond shaped and engraved with “GX EJ7” on one face.

How to take?

Lamivudine may be administered with or without food.

The recommend dose of lamivudine is 300mg daily. This is administered as either 150mg twice daily or 300mg once daily.

Missed dose

If you miss a dose of Lamivudine, take it as soon as possible. If it is within 2 hours of your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

Interactions

Lamivudine is known to interact with **Trimethoprim**, **Cladribine** and **Emtricitabine.** Although these interactions are listed they are not classed as clinically significant and so can be dispensed to the patient. Do not withhold these medicines if a patient presents with a prescription. During working hours contact SPT to discuss otherwise, dispense to patient and contact SPT at next available time.

Adverse Reactions

Lamivudine is well tolerated however, patients may present with adverse reactions: headache, insomnia, cough, nasal symptoms, nausea, vomiting, abdominal pain or cramps, diarrhoea, rash, alopecia, joint pain, muscle disorders, fatigue, malaise and fever.

RITONAVIR (NORVIR®)

Each Norvir 100mg tablet is white, oval, film coated, embossed with [Abbott logo] on one side and "NK" on the other side.

How to take?

Ritonavir is dosed as a pharmacokinetic enhancer – a medication used to boost the effectiveness of another drug.

The dose of Ritonavir will vary depending on the regime being followed. It should always be co-administered at the same time as another agent.

Ritonavir should be ingested with food, swallowed whole and not chewed, broken or crushed.

Missed dose

Take the missed dose as soon as possible. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

Interactions

Ritonavir has high affinity for several cytochrome P450 (CYP) isoforms.

Co-administration of ritonavir and medicinal products metabolised by CYP3A may result in increased plasma concentrations of the other medicine which could increase and or prolong its therapeutic and adverse effects.

Contraindicated medicines include: **colchicine, alfuzosin, amiodarone, fleclanide, pethidine, piroxicam, fusidic acid, clozapine, pimozide, quetiapine, ergotamine, simvastain, lovastatin, vardenafil, sildenafil, diazepam, flurazepam, midazolam, St John's Wort.**

The above list is not exhaustive and there are many non-contraindicated interactions when Ritonavir is co-administered with other medicines.

Always check and or refer to SPT for any new medicines commenced – prescribed, over the counter, herbal and recreational medicines.

Adverse Reactions

Very common	**Common**
Taste disturbances	Urticaria
Oral and peripheral parasthesia	Insomnia
Headache	Anxiety and confusion
Dizziness	Disturbance in attention and seizures
Peripheral neuropathy	Blurred vision
Pruritis	Anorexia and weight loss
Rash (erythematous and macopapular)	Increased urination and renal impairment

Fatigue	Flatulence
Flushing	Mouth ulcers
Feeling hot	Acne
Abdominal pain	GORD
Nausea and Vomiting	Menorragia
Diarrhoea	Fever
Joint and back pain	Hypertension or hypotension
Sore throat	Decreased white blood cells, haemoglobin, neutrophils. Increased eosinophils and thrombocytopenia
Cough	Hyperchloesterolaemia
	Gout
	Oedema

TRIUMEQ®

Triumeq® is a fixed-dose combination medicine used for the treatment of HIV infection. Each tablet contains

1. **Dolutegravir 50mg**– an integrase inhibitor
2. **Abacavir 600mg**- a nucleoside reverse transcriptase inhibitors
3. **Lamivudine 300mg–** a nucleoside reverse transcriptase inhibitors

Triumeq® is an oval, purple tablet with a curved top and bottom. It is coated with a hard film and has 572 Tri' in raised characters on one side. Triumeq is for adults and children >12years and weighing >40kg with HIV. Patients who weigh less than 40kg should not take Triumeq®.

Due to the risk of serious hypersensitivity reactions patients will be assessed by a consultant before being commenced on Triumeq and the appropriateness of treatment – see abacavir monograph.

How to take Triumeq® ?

Patients will take one tablet once daily, preferably at the same time each day if possible. It can be taken with or without food.

Missed dose

If a dose is missed it should be taken as soon as possible unless the next dose is within 4 hours. Carry on as normal with the next dose. Do not take a double dose to make up for a missed one.

Hypersensitivity reactions

Abacavir and Dolutegavir can cause a serious hypersensitivity reaction. This hypersensitivity reaction is linked to the presence of the gene HLA-B*5701 which will have been tested for before being prescribed Triumeq.

Hypersensitivity reactions observed for each products share some common features such as fever and/or rash with other symptoms indicating multi-organ involvement.

Time to onset was typically 10-14 days for both Abacavir and Dolutegavir-associated reactions, although reactions to Abacavir may occur at any time during therapy.

Patients are supplied with an 'alert card' to carry on their person.

Presentation with a **RASH and one of the following symptoms must be reported** to the Brownlee Specialist team:

- FEVER
- FEELING UNWELL OR EXTREMLEY TIRED
- MUSCLE AND JOINT PAIN
- BLISTERING OF THE SKIN
- CONJUNCTIVITIS
- MOUTH ULCERS
- SWELLING OF THE EYES, MOUTH, THROAT OR FACE
- YELLOWING OF THE SKIN OR EYES
- DARK URINE
- PALE STOOLS

Most often side effects are mild and often transient.

Interactions

ARVs can interact with other medicines, including some non-prescription medications and herbal medicines.

Triumeq® is recommended to be administered 2 hours before or 6 hours after taking any antacids, calcium or iron supplements.

- Triumeq® may interact with and dose adjustments will need to be considered by the SPT:

	Abacavir	**Dolutegavir**	**Lamivudine**
Anti-depressants	No	**Yes – St Johns Wort (contraindicated)**	No
Anti-bacterials	Yes – Rifampacin	Yes – Rifampacin	Yes – Trimethoprim
Anti-virals	Yes – Ribavirin	Yes – Efavirenz Etravirine Tipranavir Fosamprenavir Nevirapine	Yes - Emtricitabine
Anti-epileptics	Yes – Phenobarbital Phenytoin Primidone	Yes- Carbamazepine Phenytoin Oxcarbazpine Phenobarbital Primidone	No
Orlistat	Yes	No	Yes
Anti-diabetics*	Yes – Metformin*	Yes – Metformin*	No
Cytotoxics	No	No	**Yes – Cladribine (contraindicated)**

- Abacavir and Dolutegavir can increase **metformin** concentrations and a dose adjustment of **metformin** may be required.

Driving

Patients should be informed that dizziness has been reported during treatment with Dolutegravir. The clinical status of the patient and the adverse reaction profile of Dolutegravir should be borne in mind when considering the patient's ability to drive or operate machinery.

Adverse reactions

Patients may present with adverse reactions: headache, diarrhoea, nausea, vomiting, insomnia, dizziness, cough, nasal symptoms, abdominal cramps, alopecia, joint pain, muscle disorders, fatigue.

TRUVADA®

Truvada® is a fixed dose combination of 2 ARVs – (Emtricitabine 200mg and Tenofovir disoproxil fumarate 300mg).

Truvada® is a blue, capsule-shaped, film-coated tablet, debossed on one side with "GILEAD" and on the other side with "701"

Truvada® is used in patients weighing ≥35kg with HIV-1 in combination with other retroviral agents.

How to take?

Patients will take one tablet once daily, preferably around the same time each day, with food to enhance absorption.

If patients have difficulty swallowing, Truvada® can be dissolved in approximately 100mls of water, orange juice or grapefruit juice, and taken immediately.

Missed doses

If a dose of Truvada® is missed within 12 hours of the time it is usually taken, it should be taken as soon as possible, and the normal dosing schedule should be resumed.

If a dose of Truvada® is missed by **more than 12 hours**, the missed dose **should not be taken,** and the usual dosing schedule should be resumed.

If vomiting occurs within 1 hour of taking Truvada®, another dose should be taken. If vomiting occurs more than 1 hour after taking Truvada® a second dose should not be taken.

Interactions

Truvada® interacts with **Orlistat** which reduces Truvada® absorption and is not recommended for use with together.

The manufacturer advises to avoid concomitant use of Truvada® with anti-virals **Adefovir**, **Atazanavir**, **Didanosine**, **Lopinavir**, **Telaprevir** and **Lamividuine**.

Avoid regular **NSAIDs** or **nephrotoxic medicines**.

Adverse Reactions

Headache, dizziness, diarrhoea, bloating, flatulence, vomiting and nausea are all reported as very common.

These symptoms should subside after 1-2 weeks.

Renal parameters will be closely monitored by the clinical team.

Ordering Medicines

Patients already taking ARVs will be provided with 30 day supply of ARVs on enrolment to the initiative to allow time for the community pharmacy to source the anti-retrovirals.

Information for ordering medications will be directed from the Community Pharmacy Development Team.

Further up-to-date information is available:

http://www.staffnet.ggc.scot.nhs.uk/Acute/Division%20Wide%20Services/Pharmacy%20and%20Prescribing%20Support%20Unit/Community%20Pharmacy/Pages/default.aspx

Ordering Enquiries:	Community Pharmacy Development Team:	0141-232-1704
E-mail:	GG-UHB.cpdevteam@nhs.net	

Appendix 1

NHS Greater Glasgow and Clyde

Requisition for transfer of ARV Drugs where a patient changes pharmacy/ceases treatment

Originating Pharmacy Details:

Name of Pharmacist (Print):	
Signature:	
GPhC Registration Number:	
Contractor Code:	

Date of Transfer:	

Details of Drugs Transferred:

Item Name and Formulation	**Size/Strength**	**Quantity**	**Pharmacy Endorsement**

Receiving Pharmacy Details:

I confirm I have received and taken into stock, the drugs detailed above for the purpose of initiating treatment for a patient referred from the Brownlee:

Name of Pharmacist/(Tech in Brownlee) (Print):	
Signature:	
GPhC Registration Number:	
Contractor Code:	

A copy of this form to be sent to Janine Glen along with ARV invoice from original pharmacy.

The completed form to be sent to Janine Glen from receiving pharmacy.