

## Direct Acting Anti-Virals

(Sofosbuvir (Sovaldi), Sofosbuvir/ledipasvir (Harvoni), Simeprevir (Olysio), Daclatasvir (Daklinza), Ombitasvir, Paritaprevir, Ritonavir (Viekirax), Dasabuvir (Exviera))

Concordance	
<p><b>Is the patient taking their medicine(s) as prescribed?</b></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><b>Does the patient know what to do if they miss a dose?</b></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>	<p><b>Sovaldi (Sofosbuvir)</b> – given once a day at dose of 400mg daily. Not to be given as monotherapy. Always to be given with ribavirin +/- pegylated interferon. Duration is usually 12 weeks but rarely may be 24 weeks. Patients have a window to take a missed dose of 18 hours after which the dose should be omitted for that day.</p> <p><b>Harvoni (Sofosbuvir/Ledipasvir)</b> – give once daily at dose of combination tablet of sofosbuvir 400mg and ledipasvir 90mg. Can be given as monotherapy in some patient groups or in combination with ribavirin. Should not be given with Olysio. Duration is usually 8 or 12 weeks but rarely may be 24 weeks. Patients have a window to take a missed dose of 18 hours after which the dose should be omitted for that day.</p> <p><b>Olysio (Simeprevir)</b> – Dose is 150mg once daily for 12 weeks. Not to be given as monotherapy. Always to be given with combination of sofosbuvir, peg interferon, ribavirin. Patients have a window to take a missed dose of 12 hours after which the dose should be omitted for that day.</p> <p><b>Daclatasvir (Daklinza)</b> – Only rarely used. The recommended dose of Daklinza is 60 mg once daily, to be taken orally with or without meals. Not to be given as monotherapy. Always to be given in combination with either sofosbuvir, interferon, ribavirin or triple therapy. Usually given for 12 weeks but can be for 24 weeks. Patients have a window to take a missed dose of 20 hours after which the dose should be omitted for that day. Dose can be adjusted from 30-90mg depending on interactions. This can only be done on advice of a consultant hepatologist.</p> <p><b>Ombitasvir, Paritaprevir, Ritonavir (Viekirax)</b>, The recommended oral dose of Viekirax is two 12.5 mg / 75 mg / 50 mg tablets once daily with food. Viekirax should be used in combination with other medicinal products for the treatment of HCV. It is usually used for 12 weeks but can be used for 24 weeks. It is most commonly used in combination with Dasabuvir (Exviera) and ribavirin. In the case a dose of Viekirax is missed, the prescribed dose can be taken within 12 hours. If more than 12 hours have passed since Viekirax is usually taken, the missed dose should NOT be taken and the patient should take the next dose per the usual dosing schedule. Patients should be instructed not to take a double dose.</p> <p><b>Dasabuvir (Exviera)</b>. The recommended dose of dasabuvir is 250 mg (one tablet) twice daily (morning and evening). Exviera must not be administered as monotherapy. Exviera should be used in combination with other medicinal products for the treatment of HCV. Dasabuvir must always be administered together with ombitasvir/paritaprevir/ritonavir (Viekirax). In case a dose of Exviera is missed, the prescribed dose can be taken within 6 hours. If more than 6 hours have passed since Exviera is usually taken, the missed dose should NOT be taken and the patient should take the next dose per the usual dosing schedule. Patients should be instructed not to take a double dose.</p> <p>Where <b>pegylated interferon/ribavirin</b> to be given concurrently, these will either be dispensed and supplied via FVRH or on a prescription through the community pharmacy. Professional/clinical check will have been done on the regimen by hepatology team and hepatology pharmacist in FVRH prior to community pharmacist receiving script.</p> <p><b>A dose should never be doubled.</b></p> <p><b>Actions:</b></p> <p><b>Ensure that the patient knows:</b></p> <ul style="list-style-type: none"> <li>• What dose of medicine to take</li> <li>• When to take it. Is it supervised or not?</li> <li>• What to do if a dose is missed - If 1 day missed then contact hepatology team.</li> </ul> <p><b>Record any care issues in the patient's care plan and agree desired outcomes and actions.</b></p>

Generic Risk Assessment for PCR Tool

<p><b>Interactions</b></p>	<p>Please see <a href="http://www.hep-druginteractions.org">www.hep-druginteractions.org</a> and <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> for up to date interactions with direct acting antiviral medicines in hepatitis C and patients other medicines. Contact the hepatology team/hepatology pharmacist if patient is started on any new medicines either prescribed, OTC, herbal or if you suspect illicit use during therapy.</p> <p>Patients will have had pre-treatment interaction screen done by hepatology team/hepatology pharmacist prior to initiation on therapy.</p> <p><b>Harvoni</b> – interactions include antacids, PPIs, carbamazepine, phenytoin, digoxin, HIV medicines, rifampicin, statins, St. Johns Wort, Simeprevir (Olysio®).</p> <p><b>Sovaldi</b> - interactions include carbamazepine, phenytoin, rifampicin, St. Johns Wort.</p> <p><b>Olysio</b> – interactions include antiarrhythmics, carbamazepine, phenytoin, warfarin, macrolides, calcium channel blockers, St. Johns Wort, milk thistle, Anti retrovirals, statins.</p> <p><b>Daklinza</b> – Daklinza is contraindicated in combination with medicinal products that strongly induce CYP3A4 and P-gp, e.g. phenytoin, carbamazepine, rifampicin, systemic dexamethasone, and the herbal product St John's wort and thus may lead to lower exposure and loss of efficacy of Daklinza</p> <p><b>Viekirax</b> – there are <b>multiple</b> interactions with this product and <b>NO</b> medicine should be started without checking. <b>Medicines you must not take with Viekirax Include</b> amiodarone, atorvastatin, simvastatin, carbamazepine, phenytoin, clarithromycin, colchicine, ethinylestradiol-containing medicines, salmeterol for asthma, St. John's Wort (<i>hypericum perforatum</i>)</p> <p><b>Exviera</b> - carbamazepine, phenytoin, ethinylestradiol containing medicines, St. John's Wort (<i>hypericum perforatum</i>).</p> <p><b>This list is not exhaustive and you should refer to the specialist team above so that the sources can be checked for advice.</b></p> <p><b>Action:</b></p> <ul style="list-style-type: none"> <li>• Advise the patient to always check with their GP and / or pharmacist that any new medicine, including an OTC medicine, is safe to take with treatment regimen.</li> </ul> <p><b>Record any care issues in the patient's care plan and agree desired outcomes and actions.</b></p>
<p><b>Is the patient aware to make hepatology team/community pharmacist aware of any new medicines initiated during treatment course?</b></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>	

Generic Risk Assessment for PCR Tool

<p><b>Side Effects</b></p>	<p>See <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> for accurate list of side effects and for side effects of concomitant medicines in their treatment regimens. Pegylated interferon and ribavirin are often more likely to cause side effects than the direct acting antivirals (Sovaldi, Olysio, Harvoni, Daclinz, Viekirax, Exviera).</p> <p><b>Harvoni – Very common:</b> (may affect more than 1 in 10 people) - headache, tiredness</p> <p><b>Olysio - Very common:</b></p> <ul style="list-style-type: none"> <li>- feeling sick (nausea)</li> <li>- itching of the skin</li> <li>- skin rash</li> <li>- being short of breath.</li> </ul> <p><b>Sovaldi - Very common</b></p> <ul style="list-style-type: none"> <li>- fever, chills, flu-like symptoms</li> <li>- diarrhoea, feeling sick (nausea), being sick (vomiting)</li> <li>- trouble sleeping (insomnia)</li> <li>- feeling tired and irritable</li> <li>- headache</li> <li>- rash, itchy skin</li> <li>- loss of appetite</li> </ul> <p><b>Daclatasvir – Very common</b></p> <ul style="list-style-type: none"> <li>- headache</li> <li>- nausea</li> <li>- fatigue</li> </ul> <p><b>Viekirax – Very Common</b></p> <ul style="list-style-type: none"> <li>- feeling tired</li> <li>- nausea</li> <li>- itching</li> <li>- insomnia</li> <li>- lack of energy</li> </ul> <p><b>Exviera – Very common</b></p> <ul style="list-style-type: none"> <li>- feeling tired</li> <li>- nausea</li> <li>- itching</li> <li>- insomnia</li> <li>- lack of energy</li> </ul> <p>Agents may have greater adverse effects reported when they are given with pegylated interferon/ribavirin.</p> <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• <b>Check the patient’s understanding of the side effects of the medicines.</b></li> <li>• <b>Refer a patient with serious side effects or who is concerned to the hepatology team.</b></li> <li>• <b>Record any care issues in the patient’s care plan and agree desired outcomes and actions.</b></li> </ul>
<p><b>Monitoring</b></p>	<p>The monitoring of the patient and their treatment regime will be the responsibility of the Hepatology Team. See additional sheet for contact information.</p>
<p><b>Summary</b></p>	<p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• <b>Any pharmaceutical care issues, desired outcomes and actions to resolve the issues should be agreed with the patient and recorded in their care plan.</b></li> <li>• <b>At each future dispensing:</b> <ul style="list-style-type: none"> <li>○ <b>Check for concordance, interactions, side effects.</b></li> <li>○ <b>Review and update any outstanding care issues in the care plan if appropriate.</b></li> </ul> </li> </ul>
<p><b>Is the patient aware of common side effects of their medicine(s)?</b></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>	<p><b>Please annotate any pharmaceutical care issues of note?</b></p> <p><input type="checkbox"/> <b>Concordance</b></p> <p><input type="checkbox"/> <b>Interactions</b></p> <p><input type="checkbox"/> <b>Side Effects</b></p>