April 2017
Vol. 14 No. 2

NHS Forth Valley

ADTC Newsletter
New Drugs & Therapeutic Advances

Outlined below in this newsletter are the recommendations for new drugs which have been through the locally agreed process (see appendix I).

Please remember that the ADTC advises prescribers **not** to prescribe any drug that has been rejected by Scottish Medicines Consortium (SMC) or has not yet been considered by SMC.

Where a medicine is not recommended for use by the Scottish Medicines Consortium (SMC) for use in NHS Scotland, including those medicines not recommended due to non-submission, this will be noted by the Area Drug and Therapeutics Committee New Drug Sub Group and the medicine will not be added to the NHS Forth Valley Formulary.

Where a medicine that has not been accepted by the SMC or NHS Health Improvement Scotland (HIS) following their appraisal on clinical and cost-effectiveness, there is a Individual Patient Treatment Request (IPTR) process which provides an opportunity for clinicians i.e. hospital Consultants or General Practitioners to pursue approval for prescribing, on a "case by case" basis for individual patients

A copy of this policy can be found at the Pharmacy page on the Intranet on the following link:
http://intranet.fv.scot.nhs.uk/web/FILES/Pharmacyfiles/NHSFVIPTRpolicywithappendicesv1_3final.pdf

GUIDELINES AND POLICIES

All guidelines and policies approved by the Area Drug and Therapeutics Committee can be found on the Quality Improvement Website on the link below.

http://www.qifv.scot.nhs.uk/

Drugs Not Approved By the Scottish Medicines Consortium

Prescribing of SMC non-recommended drugs is monitored nationally by the Information Services Directorate (ISD) of the NHS National Services Scotland and reported to the Forth Valley Primary Care Pharmacy Services. As part of our locally agreed process, practices will be routinely notified on a quarterly basis of any items which are not recommended for use, and advised to review therapy.

The Acute Services will similarly be monitoring the use of SMC non-recommended drugs and will feedback usage to their Executives via the Finance Report.

SMC Independent Review Panel

Where there are no significant new data or analyses, the sponsor company may ask that SMC convenes an Independent Review Panel (IRP) to look again at the existing data and analyses. An IRP may only be requested after a first SMC assessment has been completed, but can then be requested at any time when the drug is not in an SMC assessment process.
The IRP will be appointed by the SMC on the advice from the Chairman and Secretariat, and shall comprise 7 members:

- 3 members (where possible) appointed from the SMC/NDC (people who, by reason of absence, have not previously been involved in the particular submission, including former members of SMC or NDC), one of whom shall be appointed to chair the panel.
- 4 members (or more if required) appointed from Scottish Area Drug and Therapeutics Committees (or their successors/equivalents) and/or other respected experts in the relevant scientific field, who need not necessarily be working in Scotland.

The IRP will review the original submission(s) considered by the pharmacy and health economic assessment teams, the output from these review teams and the views of the NDC and SMC. Should support and advice be

required then this shall be provided by the usual Assessment Teams, but will be provided by persons not involved in the original review(s)/ assessment(s).
The timeline from notification to request an IRP and publication of the final SMC advice is expected to be at least 6 months, due to the requirement to convene the panel and chair.
The IRP will report back to the SMC who shall remain the final arbiter in all cases.

NICE guidance

NICE Single technology Appraisal (STA): SMC is the source of advice for Scotland on new drug therapies and the NICE STA process therefore has **no status in Scotland**. If a NICE STA endorses a drug that was not recommended by the SMC, it is open to the manufacturers to resubmit the drug to SMC with new evidence.

NICE Multiple Technology Appraisal (MTA): NHS Healthcare Improvement Scotland (NHS HIS) reviews MTAs and decides whether the recommendations should apply in Scotland where Healthcare Improvement Scotland (HIS) decides that an MTA should apply in Scotland, the NICE guidance supersedes SMC advice. Unlike the SMC process, MTAs examine a disease area or a class of drugs and usually contain new evidence gathered after the launch of drugs or new economic modelling.
This information is reviewed by the New Drugs group on a routine basis.

HIS Comments on NICE Single Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
No guidelines submitted				

All information provided by this newsletter constitutes the most current advice of the Forth Valley Area Drug and Therapeutics Committee. All SMC information and decisions are correct at time of issue, but may be liable to change in future.
For full SMC advice on specific drugs please refer to the SMC website **www.scottishmedicines.org**

Categories

Drugs Approved / Not Recommended By SMC

Category 1	Available in line with national guidance (link to SMC Detailed Advice Document (DAD) included)
Category 2	Available in line with local guidance for prescribing
Category 3	Available from a specialist centre in another NHS Board
Category 4	Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Category 5	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance if appropriate)
Category 6	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – date decision expected to be included

The ADTC recommends that prescribers may prescribe these drugs in accordance with SMC advice, unless they are not recommended by SMC

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Abatacept (Orencia®) 125mg solution for injection (pre-filled syringe) 125mg solution for injection in pre-filled pen 250mg powder for concentrate for solution for infusion SMC No 1230/17 https://www.scottishmedicines.org.uk/files/advice/abatacept_Orencia_Non_Sub_FINAL_Feb_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate.	**Category 4** Not available as not recommended for use in NHS Scotland
Botulinum toxin A, 50 Allergan units, 100 Allergan units, 200 Allergan units, powder for solution for injection (Botox®) SMC No 692/11 https://www.scottishmedicines.org.uk/files/advice/botulinum_toxin_A_BOTOX_2nd_Resub_FINAL_Jan_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** Prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). **SMC restriction:** use in adults with chronic migraine whose condition has failed to respond to ≥3 prior oral prophylactic treatments, where medication overuse has been appropriately managed.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Desmopressin 25 microgram, 50 microgram oral lyophilisate (Noqdirna®) SMC No 1218/17 https://www.scottishmedicines.org.uk/files/advice/desmopressin_oral_lyophilisate_Noqdirna_FINAL_Jan_2017Revised030217_for_website.pdf	**Not recommended** **Indication under review:** Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults.	**Category 4** Not available as not recommended for use in NHS Scotland
Elbasvir 50 mg, grazoprevir 100mg film-coated tablet (Zepatier®) SMC No 1203/17 https://www.scottishmedicines.org.uk/files/advice/elbasvir-grazoprevir_Zepatier_FINAL_Dec_2016_Amended_020117_for_website.pdf	**Accepted for use** **Indication under review:** Treatment of chronic hepatitis C (CHC) in adults. (The efficacy of elbasvir-grazoprevir has not been demonstrated in genotypes 2, 3, 5 and 6. Elbasvir-grazoprevir is not recommended in patients infected with these genotypes).	**Category 1** Available in line with national guidance
Evolocumab 140mg solution for injection in pre-filled pen (Repatha® Sureclick) or pre-filled syringe (Repatha® PFS) SMC No 1148/16 **Resubmission** https://www.scottishmedicines.org.uk/files/advice/evolocumab_Repatha_Resubmission_FINAL_Jan_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** in adults with primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid lowering therapies in patients unable to reach low density lipoprotein-cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or, • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
	contraindicated. **SMC restriction:** for specialist use only, when administered at a dose of 140mg every two weeks, in patients at high cardiovascular risk as follows: • patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L for primary prevention of cardiovascular events or, • patients with HeFH and LDL-C ≥3.5mmol/L for secondary prevention of cardiovascular events or, • patients at high risk due to previous cardiovascular events and LDL-C ≥4.0mmol/L or • patients with recurrent/polyvascular disease and LDL-C ≥3.5mmol/L	
Everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) SMC No 1215/17 https://www.scottishmedicines.org.uk/files/advice/everolimus_Afinitor_FINAL_Jan_2017_for_website.pdf	**Accepted for use** **Indication under review:** for the treatment of unresectable or metastatic, well-differentiated (Grade 1 or Grade 2) non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease.	**Category 1** Available in line with national guidance
Guanfacine 1mg, 2mg, 3mg & 4mg prolonged-release tablets (Intuniv®) SMC No 1123/16 https://www.scottishmedicines.org.uk/files/advice/guanfacine_hydrochloride_Intuniv_FINAL_January_2016_for_website.pdf	**Accepted for use** **Indication under review:** treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Treatment must be used as part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.	**Category 2** Available in line with local guidance for prescribing
Iron III isomaltoside 1000 (contains 50mg iron per mL) (Diafer®), solution for injection SMC No 1177/16 **Resubmission** https://www.scottishmedicines.org.uk/files/advice/iron_isomaltoside_Diafer_Resubmission_FINAL_Jan_2017_for_website.pdf	**Accepted for use** **Indication under review:** For the treatment of iron deficiency in adults with chronic kidney disease (CKD) on dialysis, when oral iron preparations are ineffective or cannot be used.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Lacosamide (Vimpat) 50mg / 100mg / 150mg / 200mg film-coated tablets / 10mg/mL solution for infusion / 10mg/mL syrup SMC No 1231/17 https://www.scottishmedicines.org.uk/files/advice/lacosamide_Vimpat_Non_Sub_FINAL_FEB_2017_for_website.pdf	**Not recommended** **Indication under review:** As monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy.	**Category 4** Not available as not recommended for use in NHS Scotland
Liposomal irinotecan hydrochloride trihydrate (as irinotecan sucrosofate salt), 5mg/mL concentrate for solution for infusion (Onivyde®)	**Not recommended** **Indication under review:** Treatment of metastatic adenocarcinoma of the pancreas, in combination with fluorouracil (5-FU) and leucovorin (folinic acid), in adult patients who have progressed following gemcitabine based therapy.	**Category 4** Not available as not recommended for use in NHS Scotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
SMC No 1217/17 https://www.scottishmedicines.org.uk/files/advice/liposomal_irinotecan_Onivyde_FINAL_Feb_2017_for_website.pdf		
Obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®) SMC No 1219/17 https://www.scottishmedicines.org.uk/files/advice/obinutuzumab_Gazyvaro_FINAL_Feb_2017_Updated_13.02.17_for_website.pdf	**Accepted for use** **Indication under review:** obinutuzumab in combination with bendamustine followed by obinutuzumab maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen.	**Category 1** Available in line with national guidance
Osimertinib 40mg and 80mg film-coated tablets (Tagrisso®) SMC No 1214/17 https://www.scottishmedicines.org.uk/files/advice/osimertinib_Tagrisso_FINAL_Jan_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC). **SMC Restriction:** in patients who have received previous treatment with an EGFR tyrosine kinase inhibitor	**Category 1** Available in line with national guidance
Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) SMC No 1204/17 https://www.scottishmedicines.org.uk/files/advice/pembrolizumab_Keytruda_FINAL_Dec_2016_amended_020117_for_website.pdf	**Accepted for restricted use** **Indication under review:** The treatment of locally advanced or metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) and who have received at least one prior chemotherapy regimen. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule.	**Category 1** Available in line with national guidance
Pitolisant (Wakix®) 4.5mg/18mg film-coated tablets SMC No 1229/17 https://www.scottishmedicines.org.uk/files/advice/pitolisant_Wakix_Non_Sub_FINAL_JAN_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of narcolepsy with or without cataplexy in adults	**Category 4** Not available as not recommended for use in NHS Scotland
Trifluridine/tipiracil (as hydrochloride), 15mg/6.14mg and 20mg/8.19mg film-coated tablets (Lonsurf®) SMC No 1221/17 https://www.scottishmedicines.org.uk/files/advice/trifluridine_tipiracil_Lonsurf_FINAL_Jan_2017_for_website.pdf	**Accepted for use** **Indication under review:** The treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-vascular endothelial growth factor agents, and anti-epidermal growth factor receptor agents.	**Category 1** Available in line with national guidance
Vernakalant (Brinavess®) 20mg/ml concentrate for solution for infusion SMC No 1222/17 https://www.scottishmedicines.org.uk/files/advice/vernakalent_Brinavess_Non_Sub_F	**Not recommended** **Indication under review:** Rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults • For non-surgery patients: atrial fibrillation ≤ 7 days duration • For post-cardiac surgery patients: atrial fibrillation ≤ 3 days duration	**Category 4** Not available as not recommended for use in NHS Scotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
INAL_Jan_2017_for_website.pdf		

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position
Alirocumab 75mg and 150mg solution for injection in pre-filled pen (Praluent®) SMC No 1147/16	**Accepted for restricted use** **Indication under review**: adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: - in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL- C goals with the maximum tolerated dose of a statin or, alone or in combination with other lipid- lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. **SMC restriction:** for specialist use only in patients at high cardiovascular risk as follows: - patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L, for primary prevention of cardiovascular events or, - patients with HeFH and LDL-C ≥3.5mmol/L, for secondary prevention of cardiovascular events or, - patients at high risk due to previous cardiovascular events and LDL-C ≥4.0mmol/L or, - patients with recurrent/polyvascular disease and LDL-C ≥3.5mmol/L.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 2** Available in line with local guidance
Cefuroxime 50mg powder for solution for injection (Aprokam®) SMC No 932/13	**Accepted for use** **Indication under review:** antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 1** Available in line with national guidance
Elbasvir 50mg, grazoprevir 100mg film-coated tablet (Zepatier®) SMC No 1203/17	**Accepted for use** **Indication under review:** Treatment of chronic hepatitis C (CHC) in adults. (The efficacy of elbasvir-grazoprevir has not been demonstrated in genotypes 2, 3, 5 and 6. Elbasvir-grazoprevir is not recommended in patients infected with these genotypes).	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 1** Available in line with national guidance

Process Flowchart (Appendix 1)

NHS FORTH VALLEY PRESCRIBING OF NEW MEDICINES FLOWCHART

This flowchart outlines the NHS Forth Valley process for the prescribing of new medicines. This follows guidance from the Scottish Government for the managed introduction and availability of newly licensed medicines in NHS Scotland