

**NHS Portsmouth CCG
South Eastern Hampshire CCG
Fareham and Gosport CCG
Portsmouth Hospitals NHS Trust
Southern Health NHS Foundation Trust
Solent NHS Trust**

**Area Prescribing Committee Meeting, 1.00pm on Friday August 20th 2021
Via Teams**

Notes

<p>4.21.1</p>	<p>Attendance Alastair Bateman (Chair), Helen McHale (secretary), Mike Stewart, Phil Foster, Jon Durand, Luke Groves, Jason Peett, Sarah Nolan, Nick Moore, Ope Owoso, Vanessa Lawrence, Simon Ward (on behalf of John Knighton), Matthew Puliyeel, Chrissie Minnis (presented a document), Susan Clarke (presented a document)</p> <p>Apologies for absence Simon Cooper, Nicola Hill, Tin Orchel</p>	
<p>4.21.1.1</p>	<p>Declarations of Interest None received</p>	
<p>4.21.2</p>	<p>DRAFT Notes of last meeting It was highlighted that the entry for the Cholinesterase guideline needed an amendment to recommend that that secondary care prescribers may initiate these drugs in patients who have their medication in monitored dosage systems but will need to liaise closely with the patients usual pharmacy rather than the patients GP to ensure there are no delays including them in the system. Otherwise the notes were accepted as correct.</p> <p>Action Log</p>  <p>APC action log August 2021.xlsx</p>	 <p>APC corrected notes June 2021.doc</p>
<p>4.21.3</p>	<p>Matters arising</p> <p>SLT Thickeners requesting process The task of finalising the referral process on the primary care prescribing systems has been handed over to SLT. The document should be submitted to APC for noting when this process has been finalised and included in it.</p> <p>Management of high INRs in primary care Work is ongoing with regards the out of hours provision of vitamin K for this guideline.</p> <p>Chairs action since previous meeting Cholinesterase Guideline</p>	

	<p>The changes requested by APC in June have been made and the guideline was noted by the committee for publication.</p> <p>It was noted that work is ongoing with regards ECG availability in OPMH Community Mental Health Trusts.</p>	
4.21.4	Formulary Management – applications for approval	
4.21.4.1	<p>Vagirux – estradiol 10mcg tablets – cost efficiency compared with vagifem</p> <p>Vagirux has been highlighted to the committee as a cost efficient form of prescribing estradiol 10mcg tablets in primary care compared with vagifem. It also has the additional benefit of reduced environmental impact as it contains a reusable applicator rather than 1 applicator per dose.</p> <p>It is recognised that currently the majority of prescribing of estradiol 10mcg tablets is done by brand name and so prescribing systems may need to be adjusted to encourage prescribing of vagirux over vagifem.</p> <p>Secondary care will continue to use vagifem.</p> <p>APC decision</p> <p>The formulary entry for vagifem will be amended to Estradiol 10mcg tablets (vagifem/vagirux) with a comment to say that vagirux is the most cost efficient preparation in primary care. The formulary status will remain as green.</p>	
4.21.4.2	<p>Levetiracetam injection</p> <p>Presented by Helen McHale</p> <p>The committee received an application to include intravenous levetiracetam on the formulary. Currently the oral preparations are on the formulary however the IV preparation is not. Injectable levetiracetam is used by several departments around the Trust and also in the community for palliative patients and is a valuable option when the oral route is not available.</p> <p>APC decision</p> <p>The committee supported the application to add levetiracetam IV to the formulary as an amber recommended drug.</p>	
4.21.4.3	<p>Sandocal 1000 name change to Calvive</p> <p>Presented by Helen McHale</p> <p>It was brought to the committee's attention that the name of Sando Cal 1000 has changed to Calvive 1000. The price of the product remains the same.</p> <p>APC decision</p> <p>The committee noted the name change. The formulary entry for sandocal will be changed to Calvive 1000.</p>	
4.21.4.4	<p>Rybelsus formulary status review</p> <p>Requested by Iain Cranston</p> <p>The committee was presented with data on rybelsus prescribing to support a request to change the prescribing status from "amber recommended" to "green with a recommendation to request specialist advice if seeking to switch patients from injectable to oral".</p>	

	<p>It was noted that the data presented did not provide a detailed picture of prescribing in the area as information for practices in Fareham and Gosport and South East Hampshire had been included with data for Hampshire, Southampton and Isle of Wight CCG. Therefore it was felt the formulary status was not affecting prescribing of the drug.</p> <p>APC decision The committee felt it was comfortable with the current formulary status of rybelsus and would remain as Amber Recommended.</p>	
4.21.5	Drug therapy and shared care guidance for approval	
4.21.5.1	<p>Management of Depression in adult inpatients at Queen Alexandra Hospital Submitted by Catherine Charlton</p> <p>The committee received a PHUT guideline on the management of depression. This guideline previously encompassed the management of older people however its scope has been broadened to include all adults in PHUT. The guideline has been brought to APC as patients will be discharged from PHUT into the community on these drugs.</p> <p>Concerns were raised about the speed of dosing escalation of sertraline; the choice of citalopram and escitalopram in patients under 65 years of age and whether the Psych Liaison team had been involved in the development of the guideline.</p> <p>APC decision Vanessa Lawrence will review the guideline to ensure it aligns with Southern Health's Depression Management Guideline and feedback any comments and the above concerns to the author. The guideline will be brought back to APC for noting once feedback has been considered and incorporated as necessary.</p>	
4.21.6	Items for note/consultation	
4.21.6.1	<p>NICE Guidance</p> <p>NICE June 2021</p> <p>TA 705 Atezolizumab monotherapy for untreated advanced non-small-cell lung cancer</p> <p>Atezolizumab is recommended, within its marketing authorisation, as an option for untreated metastatic non-small-cell lung cancer (NSCLC) in adults if:</p> <ul style="list-style-type: none"> • their tumours have PD-L1 expression on at least 50% of tumour cells or 10% of tumour-infiltrating immune cells • their tumours do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) mutations and • the company provides atezolizumab according to the commercial arrangement. <p>Resource impact: This report is supported by a local resource impact template because the list price of atezolizumab has a discount that is commercial in confidence. The discounted price of atezolizumab can be put into the template and other variables may be amended. This technology is commissioned by NHS England. Providers are NHS hospital trusts.</p>	

Action required: The formulary entry for atezolizumab will be updated with a link to NICE TA 705.

TA 706 [Ozanimod for treating relapsing–remitting multiple sclerosis](#)

Ozanimod is not recommended, within its marketing authorisation, for treating relapsing–remitting multiple sclerosis in adults with clinical or imaging features of active disease.

Action required: Not applicable

TA 707 [Nivolumab for previously treated unresectable advanced or recurrent oesophageal cancer](#)

Nivolumab is recommended, within its marketing authorisation, for treating unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma in adults after fluoropyrimidine and platinum-based therapy. It is recommended only if the company provides nivolumab according to the commercial arrangement.

Resource impact: This report is supported by a local resource impact template because the list price of nivolumab has a discount that is commercial in confidence. The discounted price of nivolumab can be put into the template and other variables may be amended. This technology is commissioned by NHS England. Providers are NHS hospital trusts.

Action required: The formulary entry will be updated with a link to NICE TA 707

TA 708 [Budesonide orodispersible tablet for inducing remission of eosinophilic oesophagitis](#)

Budesonide as an orodispersible tablet (ODT) is recommended as an option for inducing remission of eosinophilic oesophagitis in adults.

Resource impact: NICE do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year in England (or approximately £9,000 per 100,000 population, based on a population for England of 56.3m).

This is because the overall incremental cost of treatment is low and eosinophilic oesophagitis is a rare condition affecting around 13,000 people in England.

This technology is commissioned by integrated care systems / clinical commissioning groups. Providers are NHS hospital trusts.

Action required: The formulary status of Budesonide orodispersible tablets will be changed to Red to align with other oral budesonide products and to minimise the risk of inappropriate prolonged continuation in primary care. It was noted that the NICE TA only permits its use for induction rather than induction and maintenance and so a business case will be required if its use for maintenance is required.

TA 709: [Pembrolizumab for untreated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency](#)

Pembrolizumab is recommended as an option for untreated metastatic colorectal cancer with high microsatellite instability (MSI) or mismatch repair (MMR) deficiency in adults, only if:

- pembrolizumab is stopped after 2 years and no documented disease progression, and
- the company provides pembrolizumab according to the commercial arrangement.

Resource impact: This report is supported by a local resource impact template because the list price of pembrolizumab has a commercial arrangement (commercial access agreement) discount that is commercial in confidence. The discounted price of pembrolizumab can be put into the template and other variables may be amended. This technology is commissioned by NHS England. Providers are NHS trust hospitals.

Action required: The formulary entry will be updated with a link to NICE TA 709

TA 710 [Ravulizumab for treating atypical haemolytic uraemic syndrome](#)

Ravulizumab is recommended, within its marketing authorisation, as an option for treating atypical haemolytic uraemic syndrome (aHUS) in people weighing 10 kg or more:

- who have not had a complement inhibitor before or
- whose disease has responded to at least 3 months of eculizumab treatment.

It is recommended only if the company provides ravulizumab according to the commercial arrangement

Resource impact: No significant resource impact is anticipated. This is because the technology is a further treatment option and the population size is small (the number of people eligible nationally for treatment with ravulizumab each year is less than 250).

This technology is commissioned by NHS England. Providers are tertiary care providers.

Action required: The formulary entry will be up dated to state that ravulizumab is for specialist use only – only to be prescribed/recommended by the Highly Specialist Atypical Haemolytic Uraemic Syndrome Centres.

TA 711 [Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs](#)

Guselkumab, alone or with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults whose disease has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them, only if they have:

- peripheral arthritis with 3 or more tender joints and 3 or more swollen joints
- moderate to severe psoriasis (a body surface area of at least 3% affected by plaque psoriasis and a Psoriasis Area and Severity Index [PASI] score greater than 10)

- had 2 conventional DMARDs and at least 1 biological DMARD.

Guselkumab is recommended only if the company provides it according to the commercial arrangement.

Resource impact: No significant resource impact is anticipated. NICE do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year in England (or £9,000 per 100,000 population).

This is because the technology is a further treatment option and is available at a similar price to the current treatment options. Guselkumab is commissioned by integrated care systems and clinical commissioning groups. Providers are NHS hospital trusts.

Action required: The formulary entry for Guselkumab will be updated with a link to NICE TA 711.

CG 138 [Patient experience in adult NHS services: improving the experience of care for people using adult NHS services](#)

This guideline covers the components of a good patient experience. It aims to make sure that all adults using NHS services have the best possible experience of care.

In June 2021 the recommendations on shared decision making were replaced by NICE's guideline on shared decision making. For further details, please see update information.

CG 142 [Autism spectrum disorder in adults: diagnosis and management](#)

This guideline covers diagnosing and managing suspected or confirmed autism spectrum disorder (autism, Asperger's syndrome and atypical autism) in people aged 18 and over. It aims to improve access and engagement with interventions and services, and the experience of care, for people with autism.

June 2021: NICE amended the recommendations on identification and assessment to clarify that when the Autism-Spectrum Quotient – 10 items (AQ-10) is used to assess for possible autism, the score at which the person should be offered a comprehensive assessment is 6 or above.

CG 170 [Autism spectrum disorder in under 19s: support and management](#)

This guideline covers children and young people with autism spectrum disorder (across the full range of intellectual ability) from birth until their 19th birthday. It covers the different ways that health and social care professionals can provide support, treatment and help for children and young people with autism, and their families and carers, from the early years through to their transition into young adult life.

This guideline should be used alongside autism spectrum disorder in under 19s: recognition, referral and diagnosis and autism spectrum disorder in adults: diagnosis and management.

In **June 2021**, NICE added new recommendations on interventions for feeding problems, including restricted diets to highlight the need for assessment and referral for children and young people. For more information, see the update decision.

NG 191 [COVID-19 rapid guideline: managing COVID-19](#)

This guideline covers the management of COVID-19 for children, young people and adults in all care settings. It brings together existing recommendations on managing COVID-19, and new recommendations on therapeutics, so that healthcare staff and those planning and delivering services can find and use them more easily.

On 3 June 2021 NICE added new recommendations on azithromycin to treat COVID-19 stating that it should not be used to treat COVID 19.

NG 196 [Atrial fibrillation: diagnosis and management](#)

This guideline covers diagnosing and managing atrial fibrillation in adults. It includes guidance on providing the best care and treatment for people with atrial fibrillation, including assessing and managing risks of stroke and bleeding.

On 10 June 2021, NICE amended the recommendation on using the ORBIT score to assess bleeding risk so that it links to a calculation tool that includes the full list of criteria, including reduced haemoglobin, reduced haematocrit and history of anaemia.

NG 197 [Shared decision making](#)

NICE have produced a new guideline covering how to make shared decision making part of everyday care in all healthcare settings. It promotes ways for healthcare professionals and people using services to work together to make decisions about treatment and care. It includes recommendations on training, communicating risks, benefits and consequences, using decision aids, and how to embed shared decision making in organisational culture and practices.

The guideline does not cover unexpected emergencies in which immediate life-saving care is needed. It also does not cover situations when, at the time a decision needs to be made, an adult does not have mental capacity to make a decision about their healthcare. For more information, see the NICE guideline on decision-making and mental capacity.

Recommendations

This guideline includes recommendations on:

- embedding shared decision making at an organisational level
- putting shared decision making into practice
- patient decision aids
- communicating risks, benefits and consequences

NG 198 [Acne vulgaris: management](#)

This new guideline covers management of acne vulgaris in primary and specialist care. It includes advice on topical and oral treatments

(including antibiotics and retinoids), treatment using physical modalities, and the impact of acne vulgaris on mental health and wellbeing.

Recommendations

This guideline includes recommendations on:

- information and support for people with acne vulgaris
- skin care advice
- diet
- referral to specialist care
- managing acne vulgaris
- relapse
- maintenance
- management of acne-related scarring

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TA 249 Dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation

1.1 Dabigatran etexilate is recommended as an option for the prevention of stroke and systemic embolism within its licensed indication, that is, in people with nonvalvular atrial fibrillation with one or more of the following risk factors:

- previous stroke, transient ischaemic attack or systemic embolism
- left ventricular ejection fraction below 40%
- symptomatic heart failure of New York Heart Association (NYHA) class 2 or above
- age 75 years or older
- age 65 years or older with one of the following: diabetes mellitus, coronary artery disease or hypertension.

1.2 Decide whether to start treatment with dabigatran etexilate after an informed discussion with the person about its risks and benefits compared with warfarin, apixaban, edoxaban and rivaroxaban. For people taking warfarin, consider the potential risks and benefits of switching to dabigatran etexilate taking into account their level of international normalised ratio (INR) control.

In **July 2021**, NICE updated recommendation 1.2 to include the other anticoagulants approved by NICE.

TA 275 Apixaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation

1.1 Apixaban is recommended as an option for preventing stroke and systemic embolism within its marketing authorisation, that is, in people with non-valvular atrial fibrillation with 1 or more risk factors such as:

- prior stroke or transient ischaemic attack
- age 75 years or older

- hypertension
- diabetes mellitus
- symptomatic heart failure.

1.2 Decide whether to start treatment with apixaban after an informed discussion with the person about its risks and benefits compared with warfarin, dabigatran etexilate, edoxaban and rivaroxaban. For people taking warfarin, consider the potential risks and benefits of switching to apixaban taking into account their level of international normalised ratio (INR) control.

In **July 2021**, we updated recommendation 1.2 to include the other anticoagulants approved by NICE.

TA 256 [Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation](#)

1.1 Rivaroxaban is recommended as an option for the prevention of stroke and systemic embolism within its licensed indication, that is, in people with non-valvular atrial fibrillation with one or more risk factors such as:

- congestive heart failure
- hypertension
- age 75 years or older
- diabetes mellitus
- prior stroke or transient ischaemic attack.

1.2 Decide whether to start treatment with rivaroxaban after an informed discussion with the person about its risks and benefits compared with warfarin, apixaban, dabigatran etexilate and edoxaban. For people taking warfarin, consider the potential risks and benefits of switching to rivaroxaban taking into account their level of international normalised ratio (INR) control.

In **July 2021**, NICE updated recommendation 1.2 to include the other anticoagulants approved by NICE.

TA 355 [Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation](#)

1.1 Edoxaban is recommended, within its marketing authorisation, as an option for preventing stroke and systemic embolism in adults with non-valvular atrial fibrillation with one or more risk factors, including:

- congestive heart failure
- hypertension
- diabetes

- prior stroke or transient ischaemic attack
- age 75 years or older.

1.2 Decide whether to start treatment with edoxaban after an informed discussion with the person about its risks and benefits compared with warfarin, apixaban, dabigatran etexilate and rivaroxaban. For people taking warfarin, consider the potential risks and benefits of switching to edoxaban taking into account their level of international normalised ratio (INR) control.

Section 1.2 of this TA has been updated to include the other anticoagulants approved by NICE.

TA712 Enzalutamide for treating hormone-sensitive metastatic prostate cancer

Enzalutamide plus androgen deprivation therapy (ADT) is recommended, within its marketing authorisation, as an option for treating hormone-sensitive metastatic prostate cancer in adults. It is only recommended if the company provides enzalutamide according to the agreed commercial arrangement.

Resource impact: This report is supported by a local resource impact template because the list price of enzalutamide has a discount that is commercial in confidence. The discounted price of enzalutamide can be put into the template and other variables may be amended. This technology is commissioned by NHS England. Providers are NHS hospital trusts.

Action required: The formulary entry for enzalutamide will be updated with a link to NICE TA 712

TA 713 Nivolumab for advanced non-squamous non-small-cell lung cancer after chemotherapy

Nivolumab is recommended as an option for treating locally advanced or metastatic non-squamous non-small-cell lung cancer (NSCLC) in adults after chemotherapy, only if:

- their tumours are PD-L1 positive, and
- it is stopped at 2 years of uninterrupted treatment, or earlier if their disease progresses, and
- they have not had a PD-1 or PD-L1 inhibitor before.

It is recommended only if the company provides nivolumab according to the commercial arrangement.

Resource impact: No significant resource impact is anticipated This technology is commissioned by NHS England. Providers are NHS hospital trusts.

Action required: The formulary entry for nivolumab will be updated with a link to NICE TA 713.

TA 714 [Dasatinib for treating Philadelphia-chromosome-positive acute lymphoblastic leukaemia \(terminated appraisal\)](#)

NICE is unable to make a recommendation on dasatinib (Sprycel) for Philadelphia-chromosome-positive acute lymphoblastic leukaemia in children and adults because Bristol Myers Squibb did not provide an evidence submission. We will review this decision if the company decides to make a submission.

Action required: NA

TA 715 [Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional DMARDs have failed](#)

1.1 Adalimumab, etanercept and infliximab, all with methotrexate, are recommended as options for treating active rheumatoid arthritis in adults, only if:

- intensive therapy with 2 or more conventional disease-modifying antirheumatic drugs (DMARDs) has not controlled the disease well enough and
- disease is moderate (a disease activity score [DAS28] of 3.2 to 5.1) and
- the companies provide adalimumab, etanercept and infliximab at the same or lower prices than those agreed with the Commercial Medicines Unit.

Adalimumab and etanercept can be used as monotherapy when methotrexate is contraindicated or not tolerated, when the criteria in 1.1 are met.

Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. If this initial response is not maintained at 6 months, stop treatment.

If more than one treatment is suitable, start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may vary because of differences in how the drugs are used and treatment schedules.

Take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DAS28 and make any appropriate adjustments.

Abatacept with methotrexate is not recommended, within its marketing authorisation, for treating moderate active rheumatoid arthritis in adults when 1 or more DMARDs has not controlled the disease well enough.

Resource impact: This report is supported by a local resource impact template because the companies have each agreed a regional or nationally available price reduction for adalimumab, etanercept and infliximab with the Commercial Medicines Unit. The prices are commercial in confidence. The discounted prices can be put into the

template and other variables may be amended. These technologies are commissioned by integrated care systems/clinical commissioning groups. Providers are NHS hospital trusts.

Action required: The formulary entries for adalimumab, infliximab, etanercept and abatacept will be updated with a link to NICE TA 715.

TA 716 [Nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency](#)

Nivolumab plus ipilimumab is recommended, within its marketing authorisation, as an option for treating metastatic colorectal cancer with high microsatellite instability (MSI) or mismatch repair (MMR) deficiency after fluoropyrimidine-based combination chemotherapy. It is recommended only if the company provides nivolumab and ipilimumab according to the commercial arrangement.

Resource impact: This report is supported by a local resource impact template because the list prices of nivolumab and ipilimumab have a commercial arrangement (commercial access agreement) discount that is commercial in confidence. The discounted price of nivolumab and ipilimumab can be put into the template and other variables may be amended. This technology is commissioned by NHS England. Providers are NHS trust hospitals.

Action required: The formulary entries for nivolumab and ipilimumab will be updated with a link to NICE TA 716.

TA 717 [Duvelisib for treating relapsed follicular lymphoma after 2 or more systemic therapies \(terminated appraisal\)](#)

NICE is unable to make a recommendation on duvelisib (Copiktra) for treating relapsed follicular lymphoma after 2 or more systemic therapies in adults because Secura Bio did not provide an evidence submission. We will review this decision if the company decides to make a submission.

Action required: NA

TA 718 [Ixekizumab for treating axial spondyloarthritis](#)

Ixekizumab is recommended as an option for treating active ankylosing spondylitis that is not controlled well enough with conventional therapy, or active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs), in adults. It is recommended only if:

- tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough, and
- the company provides ixekizumab according to the commercial arrangement.

Assess response to ixekizumab after 16 to 20 weeks of treatment. Continue treatment only if there is clear evidence of response, defined as:

- a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and
- a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.

Take into account any communication difficulties, or physical, psychological, sensory or learning disabilities that could affect responses to the BASDAI and spinal pain VAS questionnaires, and make any appropriate adjustments.

Resource impact: No significant resource impact is anticipated that is, the resource impact of implementing the recommendations in England will be less than £5 million per year in England (or £9,000 per 100,000 population).

This is because the technology is a further treatment option, the overall cost of treatment will be similar and NICE do not think practice will change substantially as a result of this guidance. This technology is commissioned by integrated care systems / clinical commissioning groups. Providers are NHS hospital trusts.

Action required: The formulary entry for ixekizumab will be updated with a link to NICE TA 718

TA 719 [Secukinumab for treating non-radiographic axial spondyloarthritis](#)

1.1 Secukinumab is recommended as an option for treating active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs) in adults. It is recommended only if:

- tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough and
- the company provides secukinumab according to the commercial arrangement.

1.2 Assess response to secukinumab after 16 weeks of treatment. Continue treatment only if there is clear evidence of response, defined as:

- a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and
- a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.

1.3 Take into account any communication difficulties, or physical, psychological, sensory or learning disabilities that could affect responses to the BASDAI and spinal pain VAS questionnaires, and make any appropriate adjustments.

Resource impact: No significant resource impact is anticipated. Secukinumab and some of the other treatment options have discounts that are commercial in confidence. This technology is commissioned by integrated care systems / clinical commissioning groups. Providers are NHS hospital trusts.

Action required: The formulary entry for secukinumab will be updated with a link to NICE TA 719.

NG 17 [Type 1 diabetes in adults: diagnosis and management](#)

This guideline covers care and treatment for adults (aged 18 and over) with type 1 diabetes. It includes advice on diagnosis, education and support, blood glucose management, cardiovascular risk, and identifying and managing long-term complications.

In **July 2021**, we reviewed the evidence and updated the recommendations on long-acting insulin therapy.

NG 164 [COVID-19 rapid guideline: haematopoietic stem cell transplantation](#)

The purpose of this guideline is to maximise the safety of patients who need haematopoietic stem cell transplantation and make the best use of NHS resources, while protecting staff from infection.

On **22 July 2021**, we made changes to recommendations on testing patients for viruses, including SARS-CoV-2 and repeating respiratory review in patients who test positive for, or are suspected of having COVID-19. See update information for further details.

NG 199: [Clostridioides difficile infection: antimicrobial prescribing](#)

This guideline sets out an antimicrobial prescribing strategy for managing *Clostridioides difficile* infection in adults, young people and children aged 72 hours and over in community and hospital settings. It aims to optimise antibiotic use and reduce antibiotic resistance. The recommendations do not cover diagnosis.

This guideline partially updates NICE's interventional procedures guidance on faecal microbiota transplant for recurrent *Clostridium difficile* infection.

This guideline updates and replaces technology appraisal 601 (September 2019), medtech innovation briefing 247 (February 2021) and evidence summaries: ES13 (June 2013) and ESNM1 (July 2012).

Action required: The PHUT and SCAN guidelines on *Clostridium difficile* are being updated currently to align with NICE. The formulary status of oral vancomycin and fidaxomicin were discussed and will remain as amber recommended as the current results reporting arrangements from the PHUT provide good treatment guidance and this will minimise inappropriate prescribing without referring to microbiology in primary care.

NG 200: [COVID-19 rapid guideline: vaccine-induced immune thrombocytopenia and thrombosis \(VITT\)](#)

	<p>This guideline covers vaccine-induced immune thrombocytopenia and thrombosis (VITT), a syndrome which has been reported in rare cases after COVID-19 vaccination. VITT may also be called vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) or thrombotic thrombocytopenic syndrome (TTS). Because VITT is a new condition, there is limited evidence available to inform clinical management, identification and management of the condition is evolving quickly as the case definition becomes clearer. This guideline was produced to support clinicians to diagnose and manage this newly recognised syndrome.</p>	
<p>4.21.6.2</p>	<p>EAMS <u>Tepotinib in the treatment of advanced non-small cell lung cancer (NSCLC)</u></p> <p>EAMS scheme consultation <u>Early Access to Medicines Scheme (EAMS) Consultation - GOV.UK (www.gov.uk)</u></p> <p>The committee noted the Tepotinib EAMS and consultation notice. Individuals are to feedback on the consultation process individually.</p>	
<p>4.21.6.3</p>	<p>Portsmouth Hospitals FMG update</p> <p>Semaglutide in Children The committee noted that semaglutide has been added to the formulary as a red drug for use in</p> <ul style="list-style-type: none"> ○ Type 2 diabetes mellitus in children ≥10y, not adequately controlled with diet, exercise, and metformin alone (or where metformin is contraindicated or not tolerated). <p>And/or</p> <ul style="list-style-type: none"> ○ Severe obesity* in children ≥10y with comorbidities**, where <ol style="list-style-type: none"> a) Weight management is not adequately controlled with diet, exercise, and metformin (or where metformin is contraindicated or not tolerated), or b) Exceptional circumstances prevent adherence to the above measures (e.g., severe autism, severe learning disabilities, immobility). <p><i>* Severe obesity is defined as a BMI of ≥30 kg/m² or ≥ the 95th centile for age and sex.</i> <i>** dyslipidaemia, hypertension, cardiovascular disease, obstructive sleep apnoea, dysglycaemia, diabetes mellitus, or pre-diabetes</i></p> <p>The drug would be recommended by the local paediatric diabetes/endocrine tertiary centre for appropriate patients under their care. The Paediatric Doctors at PHUT would then prescribe the semaglutide and carry out appropriate monitoring.</p> <p>It was proposed that prescribing and monitoring would be handed over to primary care once the patient transitions to adult services.</p> <p>APC decision</p>	

	<p>The committee noted the addition of semaglutide for this indication to the formulary as a red drug. However they raised concerns regarding the evidence supporting semaglutide for this indication. They also rejected the proposal that prescribing and monitoring would be handed over to primary care once the patient transitions to adult services because the drug is not licensed for this indication. This will be fed back to the requestors particularly highlighting the issues this will cause with continuation if it is started in any patient who is near to transitioning to adult services. Decisions made by DPC on the process of continuing the drug when a patient transitions to adults services will be sought.</p> <p>Indometacin unlicensed liquid – formulary alignment The committee noted that indometacin liquid has been added to the formulary with green prescribing status. This has been done to facilitate access to the drug for patients who are managed by practitioners from both Southampton and Portsmouth.</p> <p>Sucralfate – formulary alignment The committee noted that the prescribing status of sucralfate has been changed to green on the formulary. This has been done to facilitate access to the drug for patients who are managed by practitioners from both Southampton and Portsmouth.</p>	
4.21.6.4	<p>Solent update Verbal update by Luke Groves, Solent are now administering covid vaccines to people who are in the 16 to 17 year old age group and soon they will be rolling out the phase 3 booster vaccine. The Isle of Wight vaccine hub will soon be closing. Preparations for Solent community nursing team to administer the covid neutralising antibody are in progress. EPMA is in progress with roll out expected in November.</p>	
4.21.6.5	<p>Southern Health update Verbal update by Vanessa Lawrence, Southern Health will also be rolling out the covid neutralising antibody and will collaborate with Solent on this. Progress with work on the EPMA system is ongoing. A stand alone EPS pilot is planned to start in the next year.</p>	
4.21.6.6	<p>DPC update (June 2019) The committee noted the DPC minutes.</p>	
4.21.6.7	<p>MEC update None received</p>	
4.21.6.8	<p>Wound Formulary update The committee noted that Jobst (Essity) Leg Ulcer Hosiery Kits and Liners would be the formulary product of choice, replacing Activa Leg Ulcer Hosiery Kit and Liners. The link to the wound formulary from Portsmouth Area Prescribing formulary will be updated.</p>	
4.21.6.9	<p>Hampshire Medicines Safety Group Not received</p>	

4.21.6.10	<p>Drug Safety Update and Patient Safety Alerts The committee noted the Drug Safety Updates from June and July 2021</p>	
4.21.6.10	<p>Regional Medicines Optimisation Committees Minutes RMO London May 2021</p> <p>The minutes of the RMO London May 2021 were noted.</p> <p>The committee noted the comments that had been sent in for the RMO consultation 2 and that no comments had been sent for consultation 3.</p> <p>Shared Care Guideline consultation 4 RMO shared care guidance: draft shared care protocols, consultation 4 – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice Comments for the shared care guidelines in consultation 4 are to be sent to Helen McHale by the 5th September.</p>	
4.21.6.11	<p>NHSE Specialised Commissioning The committee noted that:</p> <ul style="list-style-type: none"> • Baricitinib for use in monogenic interferonopathies (adults and children 2 years and over), • vismodegib for adults with either Gorlin syndrome or non-Gorlin syndrome related multiple basal cell carcinomas, • abatacept for treatment of severe treatment-resistant morphea (localised scleroderma) (adults and children over 2 years) and • mercaptamine hydrochloride for corneal cystine deposits in people aged older than 2 years <p>will be commissioned for routine use.</p> <p>Baricitinib and abatacept are currently on the formulary with red prescribing status. Vismodegib will be added to the formulary as a red agent with a link to the NHS England Policy. Mercaptamine should be prescribed by specialist cystinosis centres – this will be investigated to determine the place of this drug on the formulary.</p>	
4.21.6.12	<p>Priorities committee Nil received</p>	
4.21.6.13	<p>Heal Covid Trial Presented by Chrissie Minnis An overview of the Heal Covid Trial was presented to the committee. The primary objective of HEAL-COVID is to determine whether interventions in the post-hospital (convalescent) phase of COVID-19 improve longer-term mortality/morbidity outcomes. Secondary Objectives are to evaluate treatment-specific and patient-reported outcomes of COVID-19 and their response to intervention. An additional objective is to estimate the cost-effectiveness of treatments. Patient will either receive apixaban 2.5mg bd for 14 days or atorvastatin 40mg od for a year. A letter highlighting that the patient has been started on the trial and supporting information will be sent to patients GPs.</p> <p>APC decision The committee noted that the trial protocol states that the first months supply of atorvastatin will be supplied by the hospital and subsequent supplies will be prescribed by the patients GP. Any patient who would</p>	

	<p>usually pay for prescriptions could be provided with a prepayment certificate by the Trials team. It was felt that prescription of the atorvastatin by GPs was not appropriate as the indication is not licensed. It was also highlighted that patients should be informed to take any concerns regarding the trial drugs and adverse effects to the trials team rather than to their GP. These comments will be taken back to the trial organisers.</p>	
<p>4.21.7</p>	<p>Any other business:</p> <p>Business case for Pristinamycin Presented by S Clarke</p> <p>A business case was received by the committee for the use of Pristinamycin. This drug has been included on the Solent formulary for the treatment of <i>M. genitalium</i> where other treatments have failed or cannot be used because of allergies or potential drug interactions/potential side effects. The drug will only be used and supplied by Solent Sexual Health after discussion at the MDT.</p> <p>APC decision: The committee noted Solent's decision to include pristinamycin on their formulary and will include the drug on the Portsmouth Area Prescribing Formulary with red prescribing status with a note to state this will be prescribed and supplied by Solent</p> <p>Jason Peett: NHS England are currently consulting on raising the upper age of exemption on FP10 prescriptions to 66 years old. The link to the consultation document and for providing comments is below for individuals responses.</p> <p>Aligning the upper age for NHS prescription charge exemptions with the State Pension age - GOV.UK (www.gov.uk)</p> <p>Aligning the upper age for NHS prescription charge exemptions with the State Pension age</p> <p>This consultation is seeking views on changing the upper age of age exemptions on prescription charges.</p> <p>www.gov.uk</p> <p>Helen McHale:</p> <ul style="list-style-type: none"> -The formulary entry for hydrocortisone suspension has been updated with the latest letter from PHUT providing details that the product from Cardiff manufacturing unit is the preferred product and if this is not available the Rosemont preparation can be used. -La Roche- Posay anthelios XL sunscreen has been discontinued to this will be removed from the formulary. Other alternatives listed on the formulary are still available. -A shared care leaflet has been produced by rheumatology to explain Shared Care to patients. The committee highlighted that there were several questions on the document that had not been answered and that the process for providing blood forms did not match the CCG and PHUT's shared care agreements. It was felt that these issues should be resolved and the leaflet should be sent on to the CCG pharmacists for comment prior to finalisation. 	

	Alastair Bateman: Nick Moore is to Chair the next APC meeting in October.											
4.21.8	Dates of future meetings:											
	<table border="1"> <thead> <tr> <th>2021</th> <th>2022</th> </tr> </thead> <tbody> <tr> <td>18th June</td> <td>18th February</td> </tr> <tr> <td>20th August</td> <td>15th April</td> </tr> <tr> <td>15th October</td> <td>17th June</td> </tr> <tr> <td>17th December</td> <td>19th August</td> </tr> </tbody> </table>	2021	2022	18 th June	18 th February	20 th August	15 th April	15 th October	17 th June	17 th December	19 th August	
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