NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 May 2026 at 14:30 via Microsoft Teams

APPROVED

ITEM	SUBJECT	ACTION

WELCOME

The Chair opened the meeting, welcomed members, and confirmed that a quorum was present.

1. ATTENDANCE, APOLOGIES AND DEPUTIES

Note: This item was taken later than scheduled, after item 5.6, to accommodate presenter availability.

1.1. CHAIR

Ms F Doney, Chair.

1.2. MEMBERS PRESENT

Present	Apologies	Deputies
Mr Y Al-Obaidi		
Mr G Burt from item 4		
Ms L Cameron		
Dr V Chieng		
Ms F Doney		
Dr L Elliot		
Mrs M Galvin from item 5.1		Mrs S Howlett for items 4, 5.5, 5.6
Mrs E Milne		
Mrs S O'Beirne		
Mr M Paterson from item 5.5		

1.3. IN ATTENDANCE

Ms D Bruce, Specialist Pharmacy Technician, Formulary Team.
Mrs C Standen, Formulary and Medicines Management Pharmacist.
Dr S Stone, Consultant Haematologist, for item 4.

1.4. NOTES

Members who sent apologies are recorded.

To accommodate availability and time constraints, some items were taken out of order during the meeting. For clarity and consistency, these minutes are recorded in the original agenda sequence, with annotations where applicable.

2. MINUTE AND DECISIONS

2.1. DRAFT MINUTE OF THE MEETING HELD 21 APRIL 2026

The draft minute was issued later than scheduled, members were therefore provided with an additional week to review and endorse the minutes. **ALL**

The final approved minute will be made publicly available within 21 days of formal approval. **FD**

2.2. FORMULARY GROUP DECISIONS APRIL 2026 - PUBLISHED 05/05/2026

Members formally ratified the April 2026 decisions document as published.

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3. MATTERS ARISING

3.1. ACTION LOG

The Group noted the item.

3.2. GIVINOSTAT

At the April meeting, the Group noted a query regarding whether vamorolone can be used in combination with givinostat for Duchenne muscular dystrophy (DMD).

The requestor advised that most patients receiving givinostat will already be on conventional corticosteroids (deflazacort/prednisolone). A small subgroup, very young, steroid-naïve patients started on vamorolone as first (dissociative) steroid, could in principle receive givinostat once eligible; in practice this would be boys diagnosed under 6 years and commenced on vamorolone, with givinostat added from age 6.
It was highlighted that switching from conventional steroids to vamorolone is not anticipated other than in exceptional circumstances.
The requestor confirmed that clinical trial evidence for givinostat is in combination with conventional steroids (not vamorolone) and that families will be counselled accordingly.
The requestor also noted that they could liaise with national vamorolone/givinostat discussion groups to seek advice/consensus should issues emerge.

4. DISCUSSION/PRESENTATION

Note: This item was taken earlier than scheduled, before item 1, to accommodate presenter availability.

4.1. DR STEPHANIE STONE, CONSULTANT HAEMATOLOGIST, TO DISCUSS THE REQUESTS FOR ISATUXIMAB AND BELANTAMAB FOR MULTIPLE MYELOMA

The Chair welcomed Dr Stone, Consultant Haematologist, to discuss two potentially off-label multiple myeloma treatment regimen requests.

ISATUXIMAB

Dr Stone provided members with additional information regarding the clinical rationale and protocol selection for the use of isatuximab in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Dr Stone confirmed that:

- the isatuximab in combination with bortezomib, lenalidomide, and dexamethasone regimen has been accepted by SMC for first-line treatment of multiple myeloma in patients ineligible for stem cell transplant
- the licensing study, IMROZ, had a 42-day cycle and treated people up to 80 years, so looking at a fitter population with myeloma; potentially patients in their 60s to 70s not fit enough or with borderline fitness for a stem cell transplant
- the IMROZ study used twice-weekly bortezomib and higher dexamethasone exposure, which may be poorly tolerated in older patients, particularly due to neuropathy and steroid burden
- alternative approaches (e.g., weekly bortezomib and reduced steroid dosing) are generally better tolerated, particularly by elderly patients
- locally, adoption of the BENEFIT study regimen was preferred over adapting protocols empirically, due to the availability of published randomised data demonstrating comparable progression-free survival (PFS) to IMROZ, albeit with shorter follow-up
- the BENEFIT regimen has shorter follow-up and may involve lower cumulative isatuximab exposure compared to IMROZ; however, similar efficacy is expected

- an alternative approach, the University College London (UCL) protocol, may allow equivalent isatuximab dosing but is not supported by published randomised trial data
- across the UK, most centres have adopted a 28-day cycle and weekly bortezomib for improved tolerability and service delivery. There is variation in protocol choice (e.g., BENEFIT or UCL or IMROZ-based approaches).
- the 28-day cycle is considered advantageous for service delivery, improving scheduling consistency and reducing booking errors

Members' questions were addressed.
Will patients' be advised and fully consented that this is an off-label regimen?
Dr Stone advised that, when initiating or adjusting treatment, there is routine discussion with patients regarding the balance of efficacy and tolerability, taking account of fitness/comorbidities (including neuropathy risk), and confirmed that patients would be informed. The aim of myeloma treatment is to maintain patients on treatment by maximising tolerability and response while minimising toxicity. In practice, many patients do not receive all planned treatment as prescribed.

The Chair emphasised that, for both isatuximab and belantumab, the regimens differ from the licensed/SMC dosing approach and are unlikely to meet the criteria for NCMAG consideration. The service must therefore ensure that appropriate governance arrangements are in place, with explicit patient consent and clear communication regarding the off-label use of the regimen(s).

BELANTAMAB

Dr Stone provided members with additional information regarding the clinical rationale and protocol selection for the use of belantamab in combination with bortezomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma eligible for second-line treatment for whom lenalidomide is an unsuitable treatment option.

Dr Stone and Mrs Howlett confirmed that:

- belantamab in combination with bortezomib and dexamethasone is SMC approved for relapsed refractory myeloma, only in the second-line setting
- as per the DREAM 7 trial, belantamab was given every three weeks. In the study, over 80% of patients had a grade 2 or higher ocular toxicity giving the belantamab at that interval. It took a few weeks, maybe six weeks, for the ocular toxicity to improve and therefore to be able to continue belantamab treatment.
- UCL has led the way in recommending less frequent belantamab dosing intervals
- looking at the dose intervals and efficacy, patients who achieve partial response or better are more likely to get the ocular toxicities. The response happens quickly, tends to be within six weeks, and those who need a dose reduction or a dose interval increase do not lose efficacy/have similar progression-free survival.
- the median dose interval in the studies was every 8 to 12 weeks
- the expectation is, that the service is unlikely to be dosing at the three weekly interval, it is much more likely that the second dose will be at six weeks
- looking around Scotland, it looks like most people are accepting the three-week interval on ChemoCare, but having a very low threshold for not giving that second dose
- as so many people in the trial has significant ocular toxicity, and if the median treatment is every two to three months, then it is very unlikely that treatment is going to be given every three weeks
- the service is hoping to take part in the Prommise-D trial which uses dosing every 8 weeks
- ocular monitoring is currently available for trial patients, however, access is not yet in place for NHS patients. The required documentation has been completed and submitted to Information Governance. No timeframe is currently available for approval

of the agreement to enable an optical retail provider to undertake the necessary monitoring.
- the West of Scotland Cancer Network (WoSCAN) has set up their Systemic Anti-Cancer Therapy (SACT) protocol that from cycle 3 onwards the treatment regimen moves to an 8-weekly interval
- most centres are using a 28-day treatment cycle not 21-day cycle
- there are no obvious predictors of toxicity

Members' questions were addressed.
It was noted that if treatment were set up as per the licensed schedule, consent would focus on informing patients that dosing may be withheld/adjusted if ocular toxicity develops.

During the belantamab discussion, the Chair noted that, should a less frequent dosing interval be adopted from the outset, the Group would require patient consent to be explicit and clearly documented.

The Chair thanked Dr Stone for attending the meeting to discuss the requests.
Dr Stone left the meeting prior to the decision-making process.

5. NEW PRODUCT REQUESTS

5.1. FG1SMC 2855 - BUDESONIDE (MILD TO MODERATE ACUTE ULCERATIVE COLITIS LIMITED TO THE RECTUM (ULCERATIVE PROCTITIS))

There were no declarations of interest recorded in relation to this product.

The Group considered the request for budesonide 4mg suppositories for the short-term treatment of mild to moderate acute ulcerative colitis limited to the rectum (ulcerative proctitis) in adults

The Group noted that:
- the recommended daily dose is 4mg budesonide as one 4mg suppository for six to eight weeks
- budesonide is currently included on formulary as Amber 1; Available for restricted use under specialist supervision. Treatment may be initiated in Primary Care on the recommendation of a consultant/specialist.
- the British Society of Gastroenterology notes that oral 5-aminosalicylic acid or rectal corticosteroid can be considered second-line in patients with ulcerative proctitis
- evidence for efficacy and safety comes from a randomised, double-blind, phase III study that compared budesonide 4mg suppository with budesonide 2mg rectal foam for the treatment of mild to moderate ulcerative proctitis
- the study demonstrated non-inferiority of budesonide suppository compared with budesonide rectal foam for the co-primary outcomes, clinical remission and mucosal healing
- a naïve indirect treatment comparison concluded that budesonide 4mg suppositories and prednisolone 5mg suppositories provide similar effectiveness
- the patient cohort will be treated in primary care under the guidance of the Inflammatory Bowel Disease team
- the service advised that budesonide suppositories would be used as an alternative to budesonide foam enema or oral budesonide. Oral budesonide is absorbed at the proximal intestine, resulting in low drug concentrations at the site of colonic inflammation and therefore limited effectiveness in ulcerative proctitis. Rectal administration circumvents this limitation.

The Group accepted the restricted local need for a different formulation of budesonide, 4mg suppositories, for the short-term treatment of mild to moderate acute ulcerative

proctitis in adults.

FG1SMC 2855 - Budesonide 4mg suppositories are routinely available in line with national guidance (SMC 2855).
Indication under review: for the short-term treatment of mild to moderate acute ulcerative colitis limited to the rectum (ulcerative proctitis) in adults.
Budesonide offers an additional treatment choice in the therapeutic class of topical corticosteroids.
It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist. **FTEAM**

5.2. FG1SMC 2432 – AMIKACIN (NON-TUBERCULOUS MYCOBACTERIAL LUNG INFECTIONS CAUSED BY *MYCOBACTERIUM AVIUM* COMPLEX)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for amikacin for the treatment of non-tuberculous mycobacterial (NTM) lung infections caused by *Mycobacterium avium* Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis.

The Group noted:

- amikacin liposomal nebuliser dispersion consists of amikacin encapsulated in liposomes. Amikacin is an aminoglycoside antibiotic that binds to the 30S subunit of bacterial ribosomes and interferes with an initiation complex between messenger RNA (ribonucleic acid) and the 30S subunit resulting in inhibition of protein synthesis.
- amikacin liposome inhalation dispersion as Arikayce®:
  - is the first medicine licensed for the treatment of NTM due to MAC and it is the first nebulised formulation of amikacin
  - [for this indication] meets SMC orphan criteria, and was accepted for use in NHS Scotland following a resubmission assessed under the orphan medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
  - the recommended dose is one vial (590mg) administered once daily by oral inhalation. Treatment with inhaled liposomal amikacin, as part of a combination antibacterial regimen, should be continued for 12 months after sputum culture conversion (SCC). Treatment with inhaled liposomal amikacin should not continue beyond a maximum of 6 months if SCC has not been confirmed by then.
- the Antimicrobial Management Team (AMT) supported the formulary request
- auditory and vestibular function should be monitored periodically in all patients
- the service plans to base treatment on the American Thoracic Society (ATS) guideline – '*Treatment of NTM mycobacterial pulmonary diseases: an official ATS/ERS/ESCMID/IDSA clinical practice guideline*' published in 2020. It recommends the addition of amikacin liposomal inhalation for patients with MAC pulmonary disease who have failed therapy after at least 6 months of guideline-based therapy.
- evidence comes from CONVERT, an open-label phase III study:
  - patients were randomised to guideline based therapy (GBT) plus amikacin liposomal nebuliser dispersion (ALIS) (n=224) or GBT alone (n=112)
  - the primary outcome was the proportion of patients achieving SCC, defined as three negative consecutive monthly sputum cultures, after six months treatment
  - both SCC at 6 months and sustained SCC at 3 months post-treatment were achieved by significantly more patients in the ALIS (Arikayce®) group compared with the control group
  - at 6 months, the SCC was 29% for ALIS + GBT and 8.9% for GBT alone
- patient numbers annually are expected to be small, and there are costs already in the system as treatment has been requested using the individual patient request process
- the SMC advice takes account of the benefits of a PAS that improves the cost-

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effectiveness of Arikayce®
- Arikayce® will be given instead of amikacin injection given intravenously or off-label via the nebulised route
- there are no comparative data on efficacy or safety comparing Arikayce® and amikacin injection via the nebulised route or via the parenteral route, however Arikayce® offers a licensed preparation and nebulised amikacin is associated with fewer systemic adverse effects compared to intravenous amikacin

Members highlighted uncertainty regarding responsibility and pathways for monitoring auditory and vestibular toxicity associated with amikacin. It was agreed that clarification should be sought from the service regarding monitoring arrangements, communication with primary care, patient counselling, and management of suspected adverse effects. **FTEAM**

The Group accepted the restricted local need for amikacin for the treatment of NTM lung infections caused by MAC in adults with limited treatment options who do not have cystic fibrosis, as outlined in SMC 2432.

FG1SMC 2432 - Amikacin liposomal 590mg nebuliser dispersion (Arikayce®) is routinely available in line with national guidance (SMC 2432).
Indication under review: treatment of non-tuberculous mycobacterial (NTM) lung infections (NTM-PD) caused by *Mycobacterium avium* Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. The addition of amikacin liposomal nebuliser dispersion to standard oral guideline-based therapy for MAC NTM-PD significantly increased the proportion of patients achieving sputum culture conversion at 6 months and post-treatment at 3 months. This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and managed by physicians experienced in the treatment of non-tuberculous lung disease due to MAC. **FTEAM**

5.3. FG1SMC 2839 - ZOLBETUXIMAB (HER2-NEGATIVE GASTRIC OR GASTRO-OESOPHAGEAL JUNCTION ADENOCARCINOMA)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for zolbetuximab used in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive.

The Group noted:
- zolbetuximab is a first-in-class monoclonal antibody that targets CLDN18.2. With its novel mechanism of action zolbetuximab offers a targeted treatment option for patients who would otherwise receive doublet chemotherapy alone.
- CLDN 18.2 testing is not routinely carried out locally. The service has the ability to test with appropriate requests made post-multidisciplinary team discussion.
- zolbetuximab is administered as a single loading dose of 800mg/m^2 intravenously in combination with fluoropyrimidine- and platinum-containing chemotherapy, then 600mg/m^2 intravenously every 3 weeks or 400mg/m^2 intravenously every 2 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy until

disease progression or unacceptable toxicity.

- to prevent nausea and vomiting, pre-treatment with antiemetics is recommended prior to each zolbetuximab infusion
- evidence to support the efficacy and safety of zolbetuximab comes from SPOTLIGHT and GLOW studies:
  - in SPOTLIGHT patients were randomised to zolbetuximab plus mFOLFOX6 or placebo plus mFOLFOX6
  - in GLOW patients were randomised to zolbetuximab plus CAPOX or placebo plus CAPOX
  - the primary outcome in both trials was PFS. Overall survival (OS) was a secondary outcome (zolbetuximab vs placebo).
  - in SPOTLIGHT, the median PFS improved by 2.1 months (11 months vs 8.9 months) and median OS improved by 2.6 months (18.2 months vs 15.6 months)
  - in GLOW, the median PFS improved by 1.4 months (8.2 months vs 6.8 months) and median OS improved by 2.1 months (14.3 months vs 12.2. months)
- an indirect treatment comparison showed that zolbetuximab plus chemotherapy, nivolumab plus chemotherapy and pembrolizumab plus chemotherapy all had similar hazard ratios compared with chemotherapy alone for PFS and OS. However, clinical experts consulted by SMC confirmed that zolbetuximab would rarely displace pembrolizumab or nivolumab, and would largely be used in patients who are not eligible or not suitable for immunotherapy.
- treatment should be continued until disease progression or unacceptable toxicity. The median PFS was 11 months and 8.2 months for the SPOTLIGHT and GLOW trials respectively.
- patient numbers are expected to be low, and this will be a new cost to the service, as zolbetuximab is added to standard chemotherapy
- zolbetuximab dosing is based on body surface area, so costs will vary slightly depending on the patient characteristics
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of zolbetuximab

The Group accepted the restricted local need for zolbetuximab in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumours are CLDN 18.2 positive, as outlined in SMC 2839.

FG1SMC 2839 - Zolbetuximab 100mg powder for concentrate for solution for infusion (Vyloy®)▼ is routinely available in line with national guidance (SMC 2839).
Indication under review: in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive.
In two phase III studies in adult patients with HER2-negative, locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma whose tumours were positive for CLDN18.2, the addition of zolbetuximab to chemotherapy was associated with statistically significant increases in progression-free survival.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by a physician experienced in the use of anticancer therapies. FTEAM

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5.4. FG1SMC 2808 - BLINATUMOMAB (PHILADELPHIA CHROMOSOME NEGATIVE CD19-POSITIVE B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKAEMIA (ALL) IN THE FRONTLINE CONSOLIDATION PHASE)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for blinatumomab for the treatment of adults with Philadelphia chromosome negative CD19-positive B-cell precursor acute lymphoblastic leukaemia (ALL) in the consolidation phase.

The Group noted:

- blinatumomab:
  - is a bi-specific T-cell engager antibody which binds to both CD3 expressed on the surface of patient's own T-cells and to CD19 expressed on the surface of malignant and benign B-cells
  - [for this indication] meets SMC orphan criteria, and was accepted for use in NHS Scotland following a full submission assessed under the orphan medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the service has experience in the use of blinatumomab as it is included on the formulary as monotherapy for other ALL indications
- [for this indication] blinatumomab is administered as a single cycle of treatment is 28 days (4 weeks) of continuous intravenous infusion followed by a 14 day (2 week) treatment-free interval. Patients may receive up to 4 cycles of blinatumomab consolidation treatment.
- evidence comes from E1910, an international, randomised, open-label, phase III study:
  - patients were randomised to receive standard of care consolidation chemotherapy with or without blinatumomab
  - the primary outcome was OS. After a median follow-up of 4.5 years, the addition of blinatumomab to standard of care consolidation chemotherapy resulted in a statistically significant improvement in OS.
  - the median OS was not reached in either group (HR 0.44, p=0.003), Kaplan-Meier estimated OS at 2 years was 90% for blinatumomab plus chemotherapy and 82% for chemotherapy alone
- patient numbers annually are expected to be very small, and this will be a new cost for the service as blinatumomab will be added to current standard of care chemotherapy. However, the service considers that blinatumomab will allow some patients to safely avoid some of the more toxic parts of chemotherapy treatment.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of blinatumomab

The Group accepted the restricted local need for blinatumomab for the treatment of adults with Philadelphia chromosome negative CD19-positive B-cell precursor acute ALL in the frontline consolidation phase, as outlined in SMC 2808.

FG1SMC 2808 - Blinatumomab 38.5micrograms powder for concentrate and solution for infusion (Blincyto®)▼ is routinely available in line with national guidance (SMC 2808).
Indication under review: for the treatment of adults with Philadelphia chromosome negative CD19-positive B-cell precursor acute lymphoblastic leukaemia (ALL) in the frontline consolidation phase.
In a phase III study of patients with minimal residual disease negative, Philadelphia chromosome negative, B-cell precursor ALL, the addition of blinatumomab to standard of care consolidation chemotherapy significantly improved overall survival.
This advice applies only in the context of an approved NHS Scotland Patient

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	Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated under the direction of and supervised by physicians experienced in the treatment of haematological malignancies. Patients treated with blinatumomab should be given the Educational Brochure for Patients and Caregivers and the Patient Card.	**FTEAM**

Note: Items 5.5 and 5.6 were taken earlier than scheduled, after item 4.

5.5. FG1SMC 2804 - ISATUXIMAB (ADULTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA WHO ARE INELIGIBLE FOR AUTOLOGOUS STEM CELL TRANSPLANT)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for isatuximab in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

The Group noted:

- isatuximab:
  - is an IgG1 monoclonal antibody that binds to the CD38 receptor, which is highly expressed on multiple myeloma cells, and induces cell death
  - the recommended dose of isatuximab is 10mg/kg body weight administered as an intravenous infusion
  - is already included on the formulary as a fourth-line therapy in combination with pomalidomide and dexamethasone, for the treatment of adults with relapsed and refractory multiple myeloma
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for use in NHS Scotland following a full submission assessed under the orphan equivalent medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of isatuximab
- the service plans to administer isatuximab in combination with bortezomib, lenalidomide and dexamethasone via a 28-day cycle as per the treatment protocol in the BENEFIT trial, rather than the Summary of Product Characteristics (SmPC) dosing - 42-day cycle for the first four cycles then 28-day cycles
- in the BENEFIT trial, patients received weekly bortezomib rather than twice weekly in the IMROZ trial. Weekly bortezomib has been shown to reduce the risk of peripheral neuropathy.
- the service plans to administer isatuximab over 30 minutes from the third infusion as it has been shown to have the same safety and tolerability as the infusion rates listed in the SmPC. This will save 45 minutes of chair time per infusion.
- IMROZ is an international, open-label, phase III study. Patients were randomised to receive bortezomib, lenalidomide and dexamethasone with or without isatuximab:
  - the primary outcome was PFS. After a median follow-up of 59.7 months, the median PFS was not reached in the group with isatuximab and 54 months in the group without isatuximab. The Kaplan-Meier estimated PFS at 12 months was 93% vs 86%.
  - secondary outcomes included minimal residual disease (MRD) negativity – 56% for the group with isatuximab versus 41% for the group without isatuximab
- there are no direct evidence versus relevant comparators. Indirect treatment

comparisons suggested that isatuximab has superior efficacy for PFS and OS to all comparators except daratumumab plus lenalidomide and dexamethasone in terms of OS, as the results did not suggest evidence of a difference for this outcome. Isatuximab has superior efficacy for minimal residual disease negativity [SMC].

- BENEFIT is an open-label, multicentre parallel arms phase III trial. Patients were randomised to isatuximab plus lenalidomide and dexamethasone or isatuximab plus lenalidomide, dexamethasone and bortezomib
- the primary outcome was MRD negativity at 10-5 at 18 months which was 53% for the isatuximab plus lenalidomide, dexamethasone and bortezomib arm vs 26% in the isatuximab plus lenalidomide and dexamethasone arm.
- there are differences across the BENEFIT and IMROZ studies on the cumulative dose density of bortezomib. In IMROZ, bortezomib was given on a twice-weekly schedule (24 twice-weekly infusions over a 6-month period) and in BENEFIT, bortezomib was given weekly but over a more prolonged time (48 weekly infusions over 18 months). The service requested use in line with the BENEFIT dosing schedule.
- patient numbers annually are estimated to be moderate, however if the treatment regimen is well tolerated, patient numbers are likely to increase
- in IMROZ, the median duration of treatment in the isatuximab containing group was 53.2 months
- cost off-set is available from the displacement of daratumumab, lenalidomide and dexamethasone, however the daratumumab combination will remain relevant for older and frailer patients
- if the service uses bortezomib in line with the BENEFIT study, the drug cost of bortezomib will increase. However, IMROZ would require additional nurse/chair time required for twice-weekly bortezomib administration.

Members recognised that:

- treatment does not have a curative intent
- the BENEFIT and UCL regimens would be considered off-label use
- the IMROZ 42-day cycle, creates complications with booking patients
- the 28-day cycle is advantageous for service delivery, improving scheduling consistency and reducing booking errors
- the BENEFIT protocol is backed by study data but has more peripheral neuropathy, the UCL approach may allow equivalent dosing of isatuximab [to IMROZ]
- the aim of treatment is to maintain patients on treatment for as long as possible by maximising tolerability and response while minimising toxicity. Patients having to stop treatment early due to side-effect profile(s) can restrict this significantly.
- treatment centres are managing myeloma treatment protocols to make them more tolerable and manageable

The Group acknowledged that it is standard practice for bortezomib to be administered weekly, and that switching to a 28-day cycle for all myeloma regimens is beneficial for service delivery, reducing booking errors and improving scheduling. The Group acknowledged that this aligns with most UK centres and supports safer, more manageable patient care.

The Chair highlighted the need for clear documentation of consent for off-label regimens, referencing prior concerns raised nationally where patients were not clearly informed/consented when local treatment protocols differed from standard practice.

The Group accepted the restricted local need for isatuximab used in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. Acceptance extends to off-label use in line with the BENEFIT or UCL protocols, subject to appropriate patient consent.

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	FG1SMC 2804 - Isatuximab 20mg/mL concentrate for solution for infusion (Sarclisa®) is routinely available in line with local guidance. Indication under review: in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. In a phase III study of patients with newly diagnosed multiple myeloma ineligible for autologous stem cell transplant, the addition of isatuximab to bortezomib, lenalidomide, and dexamethasone significantly improved progression-free survival. This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Isatuximab should be administered by a healthcare professional, in an environment where resuscitation facilities are available.	**FTEAM**

5.6. FG1SMC 2727 - BELANTAMAB MAFODOTIN (ADULTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA ELIGIBLE FOR SECOND LINE TREATMENT)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for belantamab in combination with bortezomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma eligible for second-line treatment for whom lenalidomide is an unsuitable treatment option.

The Group noted:

- belantamab:
  - is a humanised monoclonal antibody conjugated with a cytotoxic agent called maleimidocaproyl monomethyl auristatin F (mcMMAF)
  - is administered once every three weeks with a starting dose of 2.5mg/kg. Belantamab is administered from cycle 1 until completion of treatment, while bortezomib and dexamethasone are administered for the first eight cycles.
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for use in NHS Scotland following a full submission assessed under the orphan equivalent medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the service proposes to give belantamab at a less frequent dose interval (e.g. once every 6 or 8 weeks) as it is supported by 'real world' dose intervals within the DREAMM-7 study and did not appear to reduce efficacy
- most patients treated with belantamab mafodotin develop ocular symptoms that can impact their quality of life
- patients should have an ophthalmic examination (including visual acuity and slit lamp examination) performed by an eye care professional before each of the first four doses of belantamab, and as clinically indicated thereafter
- evidence comes from DREAMM-7, an international, open-label, phase III study:
  - patients were treated with belantamab mafodotin intravenously at a dose of 2.5mg/kg on day 1 of 21-day cycles or daratumumab intravenously. Both groups received bortezomib and dexamethasone for the first eight cycles.
  - the primary outcome was PFS – median PFS was 36.6 months in the belantamab group and 13.4 months in the daratumumab group
- an indirect treatment comparison suggest a PFS and OS benefit for belantamab mafodotin in combination with bortezomib plus dexamethasone versus the relevant comparators: daratumumab in combination with bortezomib plus dexamethasone,

carfilzomib in combination with dexamethasone and pomalidomide in combination with bortezomib plus dexamethasone
- modification of belantamab mafodotin dosing to balance efficacy and tolerability in the DREAMM-7 and DREAMM-8 trials:
  - in practice, most patients are anticipated to have grade ≥2 ophthalmic exam findings after two to three doses that will require an extended dosing interval (8-12-week interval)
  - although ocular events were common, they were effectively managed with dose modifications and were generally reversible with adequate follow-up, allowing for patients to remain on treatment
- patient numbers are expected to be small, but may increase as the service gains experience using belantamab
- the median total duration of exposure to any study medicine was 15.9 months in the belantamab mafodotin combination group and 12.9 months in the daratumumab combination group
- cost off-set is available from displacement of alternative second-line treatment options
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of belantamab

It was reported that the NICE Technology appraisal guidance TA1149 included comment that '*Clinical advice to the company at clarification also suggested that healthcare professionals may choose to start with a dosing window of every 4 weeks, extending to every 8 weeks and then every 12 weeks. So, exposure to belantamab mafodotin may be lower in NHS clinical practice. '*

The Group acknowledged that belantamab is associated with a high risk of ophthalmic side effects. It was noted that, in the licensing trial, a significant number of patients required less frequent dosing intervals, and that available data support less frequent dosing, with potential benefit to patients.

The Chair highlighted the need for clear documentation of consent for off-label regimens.

The Group accepted the restricted local need for belantamab in combination with bortezomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who are eligible for second-line treatment for whom lenalidomide is an unsuitable treatment option. Acceptance extends to potential off-label use with extended dosing intervals, subject to appropriate patient consent.

FG1SMC 2727 - Belantamab mafodotin 70mg, 100mg powder for concentrate for solution for infusion (Blenrep®)▼ is routinely available in line with local guidance.
Indication under review: in combination with bortezomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who are eligible for second line treatment for whom lenalidomide is an unsuitable treatment option.
In an open-label phase III study in patients with relapsed or refractory multiple myeloma after at least one prior line of therapy, belantamab mafodotin in combination with bortezomib plus dexamethasone was associated with statistically significant improvements in progression-free survival compared with an anti-CD38 monoclonal antibody in combination with a proteasome inhibitor and a glucocorticoid.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and

ITEM	SUBJECT	ACTION
	8b - recommended for hospital use only. Treatment with belantamab should be initiated and monitored by physicians experienced in the treatment of multiple myeloma.	**FTEAM**

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES

There were no declarations of interest recorded in relation to this product.

Mrs Standen reported that:
- apremilast as the brand Otezla® has undergone patent expiry
- multiple generic products are now available and the tablets have been included in part 7 of the Scottish Drug Tariff
- the formulary entry will be updated to remove the brand name, and the name change highlighted to the local and regional Hospital Electronic Prescribing and Medicines Administration (HEPMA) Teams.

Members supported update of the formulary entry to remove the brand name, only the generic name will be noted on the formulary. **FTEAM**

6.2. FERRIC CARBOXYMALTOSE CONTRACT UPDATE

There were no declarations of interest recorded in relation to these products.

Mrs Standen reported that, the Scottish contract for ferric carboxymaltose has changed from Ferinject® to Feristark®. Notification of the change has been issued to colleagues within the managed service.

The Group accepted the restricted local need for Feristark® and supported its addition to formulary without the need for a full submission. It was agreed that the Feristark® would be added to the formulary in alignment with the existing formulary position and accordance with the product's licensed indications.

Ferric carboxymaltose 50mg iron/mL solution for infusion (Feristark®) is routinely available in line with local guidance.
Indication under review: for the treatment of iron deficiency (children, adolescents and adults 1 year and older) when:
- **oral iron preparations are ineffective**
- **oral iron preparations cannot be used**
- **there is a clinical need to deliver iron rapidly**

The diagnosis of iron deficiency must be based on laboratory tests.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Monitor carefully patients for signs and symptoms of hypersensitivity reactions during and following each administration of Feristark®.
Feristark® should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured. The patient should be observed for adverse effects for at least 30 minutes following each Feristark® administration. **FTEAM**

Ferinject® will be noted as 'not routinely available as there is a preference for alternative medicines. **FTEAM**

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6.3. ADDITIONAL ITEM – NEXPLANON® EXTENDED DURATION OF USE

An item not included on the agenda was raised.

Ms Doney reported that the SmPC for the progestogen-only implant, Nexplanon®, has been updated to reflect an extended duration of use; increasing from up to 3 years to 5 years. Evidence supports use of the etonogestrel implant for up to 5 years, with maintained contraceptive effectiveness and no new safety concerns identified.

The Group supported an update to the formulary to reflect the extension to use of the etonogestrel implant (Nexplanon®), without the need for a full submission.

Etonogestrel 68mg implant (Nexplanon®) is routinely available in line with local guidance.
Indication under review: contraception.
One implant can be left in place for five years.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.
It is strongly recommended that Nexplanon® be inserted and removed only by healthcare professionals (HCPs) who have completed training for the use of the Nexplanon® applicator and the techniques for insertion and removal of the Nexplanon® implant, and, where appropriate, that supervision be requested prior to inserting or removing the implant. **FTEAM**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED MAY 2026

The Group noted the SMC advice published May 2026.

Following publication of the negative SMC recommendation for nemolizumab (Nemluvio®▼ - SMC 2832) and the non-submission statements for brentuximab vedotin (Adcetris® - SMC 2925), gefapixant (Lyfnua®▼ - SMC 2926), peginterferon alfa-2a (Pegasys® - SMC 2936) and peginterferon alfa-2a (Pegasys® - SMC 2937) these medicines will not be included on the Grampian Joint Formulary for the indications in question.

The following SMC accepted medicines have not been processed within a 60-day timescale:
- SMC 2834 amivantamab (Rybrevant®) (submission expected)
- SMC 2814 budesonide (Kinpeygo®▼) (submission received)
- SMC 2818 durvalumab (Imfinzi®) (submission expected)
- SMC 2842 enfortumab vedotin (Padcev®) (submission received)

Local advice for these medicines and indications will be included in the April 2026 decisions as ‘Not routinely available as the ADTC is waiting for further advice from local clinical experts’. **FTEAM**

7.2. NATIONAL CANCER MEDICINES ADVISORY GROUP ADVICE PUBLISHED APRIL 2026

The Group noted the NCMAG advice published April 2026.

The following NCMAG supported medicine has not been processed within a 60-day timescale:
- NCMAG 126 nivolumab (Opdivo®)

Local advice for this medicine and indication will be included in the May 2026 decisions as ‘Not routinely available as the ADTC is waiting for further advice from local clinical experts’. **FTEAM**

ITEM	SUBJECT	ACTION

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED MAY 2026

The Group noted the SMC provisional advice issued May 2026.

If the SMC issues negative recommendations or non-submission statements next month, these medicines will not be included on the formulary for the specified indications.

9. OTHER BUSINESS

9.1. NATIONAL GYNAECOLOGY PATHWAYS

The Group noted the item.

10. DOCUMENTS FOR INFORMATION

Items 10.1 (MHRA Safety Round-up April 2026), 10.2 (MHRA Drug Safety Update – nasal decongestant sprays and drops containing xylometazoline hydrochloride/ oxymetazoline hydrochloride: increased risk of rebound congestion, rhinitis medicamentosa, and tachyphylaxis with overuse), 10.3 (MHRA Drug Safety Update – finasteride and dutasteride - updated safety warnings for psychiatric side effects and sexual dysfunction), 10.4 (Grampian Area Drug and Therapeutics Committee meeting minute January 2026), 10.5 (Medicines Guidelines and Policies Group meeting minute February 2026) were noted.

11. AOCB

None.

DATE OF NEXT MEETING

Tuesday 16 June 2026 starting at 14.30 via Microsoft Teams.

Signature on file

CHAIR'S SIGNATURE **Dr Louise Elliot** **DATE** **16 June 2026**