

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**  
**CENTRE FOR HEALTH TECHNOLOGY EVALUATION**  
**Technology Appraisals**

**Consultation on Batch 64 draft remits and draft scopes and  
summary of comments and discussions at scoping  
workshops**

**Topic list**

**Topic ID: 1420**

Topic title: Nintedanib for treating systemic sclerosis associated with interstitial lung disease.

**Topic ID: 1212**

Topic title: Galcanezumab for preventing episodic cluster headache.

**Topic ID: 1304**

Topic title: Siponimod for treating secondary progressive multiple sclerosis.

**Topic ID: 1195**

Topic title: Crisaborole for treating mild to moderate atopic dermatitis in people aged 2 years and older.

**Topic ID: 1499**

Topic title: Solriamfetol for treating excessive sleepiness caused by narcolepsy or obstructive sleep apnoea.

**Topic ID: 1511**

Topic title: Ustekinumab for treating moderately to severely active ulcerative colitis.

**Topic ID: 1514**

Topic title: Ticagrelor for preventing cardiovascular events in people with type 2 diabetes and coronary artery disease.

**Topic ID: 1450**

Topic title: Semaglutide for treating type 2 diabetes.

**Topic ID: 1451**

Topic title: Dulaglutide for treating type 2 diabetes.

## Provisional Title: Nintedanib for treating systemic sclerosis associated with interstitial lung disease

Topic Selection ID Number: 8813.

TA ID Number: 1420.

Company: Boehringer Ingelheim.

### Anticipated Licensing Information

\*\*\*Confidential information removed\*\*\*

### Draft Remit

To appraise the clinical and cost effectiveness of nintedanib within its marketing authorisation for treating interstitial lung disease caused by systemic sclerosis.

### Main points from consultation

Following the consultation exercise and the scoping workshop, NICE is of the opinion that an appraisal of nintedanib for treating systemic sclerosis associated with interstitial lung disease is **appropriate**.

The proposed remit is not appropriate and should be amended as follows:

“To appraise the clinical and cost effectiveness of nintedanib within its marketing authorisation for treating **systemic sclerosis associated with** interstitial lung disease”

Minor amendment requested by attendees because it implied that the development of ILD is a marker of severity of SSc, whereas ILD can occur even in less severe cases of SSc. The company stated that this would also be more consistent with the wording of the proposed marketing authorisation.

Population - several settings are covered in the SENSICIS trial (untreated, those being treated (eg. with Mycophenolate), and those who have had treatment that has not been effective). The population in the scope should remain broad as the marketing authorisation wording is broad.

### Population Size

Approximately 630 to 5600 people in England would be eligible for treatment with nintedanib.

This estimate is based on 19000 to 21000 people being diagnosed in England each year with SSc, of whom between 10 and 80% are likely to develop ILD (1900 to 17000), of whom 33.3% are eligible for this treatment.

**Process (TA/HST):** TA.

### Proposed changes to remit

To appraise the clinical and cost effectiveness of nintedanib within its marketing authorisation for treating **systemic sclerosis associated with** interstitial lung disease

## Costing Implications

The list price of nintedanib is £2,151.1 for either a pack of 60, 100mg capsules or a pack of 60, 150mg capsules. \*\*\*Confidential information removed\*\*\*

## Timeliness Statement

Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

## **Provisional Title: Galcanezumab for preventing episodic cluster headache**

**Topic Selection ID Number:** 8952.

**TA ID Number:** 1212.

**Company:** Eli Lilly.

### **Anticipated Licensing Information**

\*\*\*Confidential information removed\*\*\*

### **Draft Remit**

To appraise the clinical and cost effectiveness of galcanezumab within its marketing authorisation for preventing cluster headache.

### **Main points from consultation**

Following the consultation exercise and the scoping workshop held by teleconference, NICE is of the opinion that an appraisal of galcanezumab for preventing episodic cluster headache is **appropriate**.

The proposed remit is not appropriate and should be amended as follows: The term 'episodic' should be included to make the remit consistent with the expected wording of the marketing authorisation, that is it excludes chronic cluster headache

Attendees at the scoping teleconference discussed how galcanezumab will be used in clinical practice. The population and comparators in the scope have been amended to be consistent with the expected use of galcanezumab. Minor changes have also been made to the outcomes and subgroups.

### **Population Size**

Approximately 27,400 people in England would be eligible for treatment with galcanezumab.

This estimate is based on a population in England of approximately 54.8 million and a 1-year prevalence of cluster headache being estimated at 5 per 10,000. These values were included in the Horizon Scanning Document, March 2017. There are no data on the number of people with only episodic cluster headache.

**Process (TA/HST):** TA.

### **Proposed changes to remit**

To appraise the clinical and cost effectiveness of galcanezumab within its marketing authorisation for preventing **episodic** cluster headache.

### **Costing Implications**

The unit cost of galcanezumab is unknown so the resource impact of this technology cannot currently be estimated.

## Timeliness Statement

Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

## **Provisional Title: Siponimod for treating secondary progressive multiple sclerosis**

**Topic Selection ID Number:** 8457.

**TA ID Number:** 1304.

**Company:** Novartis.

### **Anticipated Licensing Information**

\*\*\*Confidential information removed\*\*\*

### **Draft Remit**

To appraise the clinical and cost effectiveness of siponimod within its marketing authorisation for treating secondary progressive multiple sclerosis in adults.

### **Main points from consultation**

Following the consultation exercise, NICE is of the opinion that an appraisal of siponimod for treating secondary progressive multiple sclerosis is **appropriate**.

The proposed remit is appropriate. No changes are required.

The comparators in the scope have been amended to be consistent with the expected use of siponimod (stakeholders did not think best supportive care was adequate to describe current practice). Minor changes have also been made to the outcomes.

### **Population Size**

Approximately 38,000 people in the UK would be eligible for treatment with siponimod.

This estimate is based on a UK population of approximately 66 million and a UK prevalence of secondary progressive multiple sclerosis of 57.8 per 100,000. This prevalence estimate was obtained from a 2018 systematic review, which did not report data for England. Assuming the UK value is generalisable, this gives an estimated prevalence of approximately 32,000 in England.

### **Process (TA/HST): TA**

### **Proposed changes to remit**

None

### **Costing Implications**

The unit cost of siponimod is unknown so the resource impact of this technology cannot currently be estimated.

### **Timeliness Statement**

Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

## **Provisional Title: Crisaborole for treating mild to moderate atopic dermatitis in people aged 2 years and older**

**Topic Selection ID Number:** 8295.

**TA ID Number:** 1195.

**Company:** Pfizer.

### **Anticipated Licensing Information**

\*\*\*Confidential information removed\*\*\*

### **Draft Remit**

To appraise the clinical and cost effectiveness of crisaborole within its marketing authorisation for treating mild to moderate atopic dermatitis in people aged 2 years and older.

### **Main points from consultation**

Following the consultation exercise and the scoping workshop, NICE is of the opinion that an appraisal of crisaborole for treating mild to moderate atopic dermatitis in people aged 2 years and older is **appropriate**.

The proposed remit is appropriate. No changes are required.

### **Population Size**

The exact number of people aged 2 years and older with mild to moderate atopic dermatitis eligible for treatment could not be fully estimated however it is anticipated to be very high.

Approximately 240,000 children aged 5 years or older with moderate atopic eczema in England would be eligible for treatment with crisaborole.

Atopic eczema is estimated to affect approximately 1.3 million children in England. In children aged over 5 years with atopic eczema, the severity distribution is 80% mild cases, 18% moderate cases and in 2% severe cases.

### **Process (TA/HST): TA**

### **Proposed changes to remit**

None

### **Costing Implications**

The unit cost of crisaborole is unknown so the resource impact of this technology cannot currently be estimated.

### **Timeliness Statement**

Based on marketing authorisation for use in the UK, publication of timely guidance will not be possible. However information has been requested on the company's planned launch and timely guidance based on launch in the UK may still be possible.

## Provisional Title: Solriamfetol for treating excessive sleepiness caused by narcolepsy or obstructive sleep apnoea

Topic Selection ID Number: 9860.

TA ID Number: 1499.

Company: Jazz Pharmaceuticals.

### Anticipated Licensing Information

\*\*\*Confidential information removed\*\*\*

### Draft Remit

To appraise the clinical and cost effectiveness of solriamfetol within its marketing authorisation for treating excessive sleepiness caused by narcolepsy or obstructive sleep apnoea.

### Main points from consultation

Following the consultation exercise and the scoping workshop, NICE is of the opinion that an appraisal of solriamfetol for treating excessive sleepiness caused by narcolepsy or obstructive sleep apnoea is **appropriate**.

The proposed remit is not appropriate and should be amended as follows: To appraise the clinical and cost effectiveness of solriamfetol within its marketing authorisation for treating excessive **waketime** sleepiness caused by narcolepsy or obstructive sleep apnoea.

Minor amendment to add 'waketime' –suggested at scoping workshop to specify that the symptom is sleepiness interrupting their day (or equivalent for shift/night workers).

Clear consensus that the narcolepsy and OSA populations are clinically distinct and should be considered separately.

Propose that this topic is split into 2 separate STAs: (1 STA for OSA and 1 STA for narcolepsy). This is to reflect the clinically distinct populations and the different comparators for each disease.

### Population Size

Approximately 225,000 people in England with obstructive sleep apnoea would be eligible for treatment with solriamfetol. People with diagnosed/treated OSA in UK = 1.5 million \* 15% = 225,000.

### Process (TA/HST): TA

### Proposed changes to remit

STA 1: To appraise the clinical and cost effectiveness of solriamfetol within its marketing authorisation for treating excessive **waketime** sleepiness caused by **narcolepsy**.

STA 2: To appraise the clinical and cost effectiveness of solriamfetol within its marketing authorisation for treating excessive **waketime** sleepiness caused by **obstructive sleep apnoea**

## **Costing Implications**

The unit cost of solriamfetol is unknown so the resource impact of this technology cannot currently be estimated.

## **Timeliness Statement**

Based on marketing authorisation for use in the UK, publication of timely guidance may or may not be possible. NICE are unable to provide an accurate statement until confirmation of the expected MA month is provided.

## **Provisional Title: Ustekinumab for treating moderately to severely active ulcerative colitis**

**Topic Selection ID Number:** 8829.

**TA ID Number:** 1511.

**Company:** Janssen.

### **Anticipated Licensing Information**

\*\*\*Confidential information removed\*\*\*

### **Draft Remit**

To appraise the clinical and cost effectiveness of ustekinumab within its marketing authorisation for treating moderately to severely active ulcerative colitis.

### **Main points from consultation**

Following the consultation exercise, NICE is of the opinion that an appraisal of ustekinumab for treating moderately to severely active ulcerative colitis for treating is **appropriate**.

The proposed remit is appropriate. No changes are required.

Minor changes have been made to the outcomes.

### **Population Size**

Approximately 12,000 people in England would be eligible for treatment with ustekinumab.

This estimate is based on 104,000 people with ulcerative colitis, of whom the proportion with moderate to severe disease is 52% and approximately 22% of these people would be eligible for treatment with biologics.

### **Process (TA/HST): TA**

### **Proposed changes to remit**

None

### **Costing Implications**

Ustekinumab will be a treatment option alongside existing treatment options for treating moderately to severely active ulcerative colitis and therefore uptake is unknown. The list price of ustekinumab is £2,147 for both infusion vials and solution for injection pre-filled syringes. There is a PAS discount available for ustekinumab when used to treat other conditions and it is likely there will be a PAS discount available for ustekinumab when treating ulcerative colitis, therefore the resource impact is unknown.

### **Timeliness Statement**

Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

## **Provisional Title: Ticagrelor for preventing cardiovascular events in people with type 2 diabetes and coronary artery disease**

**Topic Selection ID Number:** 8382.

**TA ID Number:** 1514.

**Company:** AstraZeneca.

### **Anticipated Licensing Information**

\*\*\*Confidential information removed\*\*\*

### **Draft Remit**

To appraise the clinical and cost effectiveness of ticagrelor within its marketing authorisation for preventing cardiovascular events in people with type 2 diabetes and coronary artery disease.

### **Main points from consultation**

Following the consultation exercise and the scoping workshop, NICE is of the opinion that an appraisal of ticagrelor for preventing cardiovascular events in people with type 2 diabetes and coronary artery disease is **appropriate**.

The proposed remit is appropriate. No changes are required.

The company noted the draft remit was broad but understood that this would allow the scope to accommodate any differences between the anticipated and final marketing authorisation.

The treatment pathway was discussed in detail and it was agreed to add aspirin and clopidogrel (+/- aspirin) as comparators in the scope. It was also agreed that subgroups of people who have a higher risk of major cardiovascular events should be considered separately if evidence allowed.

### **Population Size**

It's uncertain how many patients in England would be eligible for treatment with ticagrelor. Approximately 3.1 million people have diabetes in the UK, of which 90% have type 2 diabetes. Fifty percent of people will have signs of cardiovascular disease at diagnosis however it is unknown what proportion with CVD have not had a prior CV event.

### **Process (TA/HST): TA**

#### **Proposed changes to remit**

None

#### **Costing Implications**

The annual cost of treatment with ticagrelor is around £710 per person but because uptake is unknown, the resource impact is unknown.

## Timeliness Statement

Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

## Provisional Title: Semaglutide for treating type 2 diabetes

Topic Selection ID Number: 8318.

TA ID Number: 1450.

Company: Novo Nordisk.

### Anticipated Licensing Information

Marketing authorisation granted: 08/02/2018

Launch date: Jan 2019

Wording of marketing authorisation: Treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes

### Draft Remit

To appraise the clinical and cost effectiveness of semaglutide within its marketing authorisation for treating type 2 diabetes

### Main points from consultation

Following the consultation exercise, NICE is of the opinion that an appraisal of semaglutide for treating type 2 diabetes is **not appropriate**.

There were mixed views from stakeholders about the value of conducting an appraisal. Only the company of semaglutide highlighted a strong need to progress with a single technology appraisal (because of clinical advantages over second and third line therapies). By contrast, the company of dulaglutide (also being considered for referral in this batch) believes an appraisal of both technologies should not be considered a priority given the clear and effective guidance on the use of GLP-1 mimetics in NICE guideline 28 and given that these are the 6<sup>th</sup> and 7<sup>th</sup> drugs in the class. A clinical guideline update would be of more value, incorporating the positive effects of all GLP-1 mimetics on cardiovascular risk and in renal dysfunction (the most important new data to emerge for this class), once fully available.

A comparator company (of a SGLT2 inhibitor) believes it would only be appropriate to refer this topic for appraisal if it is an MTA that includes SGLT2 inhibitors and other GLP1 mimetics as interventions, and incorporating new cardiovascular outcomes data. This stakeholder is concerned that, if all available evidence is not considered, there is a risk of disadvantaging patients by altering the treatment pathway in a way that is not reflective of current evidence or current clinical practice.

There were no comments from patient or professional groups.

### Population Size

Over 3 million people in England could be eligible for treatment with semaglutide because there were over 3.1 million people in England with diagnosed type 2 diabetes mellitus in 2017.

**Process (TA/HST):** N/A – referral not sought. Topic to be incorporated in clinical guideline update.

## **Proposed changes to remit**

N/A – referral not sought

## **Costing Implications**

The list price of semaglutide is around £70 for 1 pen containing 4 x once-weekly doses. This results in an annual cost of around £950 per person. However, potential uptake of semaglutide is unknown and therefore the resource impact is unknown.

## **Timeliness Statement**

N/A – referral not sought.

## Provisional Title: Dulaglutide for treating type 2 diabetes

Topic Selection ID Number: 6285.

TA ID Number: 1451.

Company: Eli Lilly.

### Anticipated Licensing Information

Marketing authorisation granted: 21st November 2014, launched in the UK in 2015.

Wording of marketing authorisation: Indicated in adults with type 2 diabetes mellitus to improve glycaemic control as:

- monotherapy when diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications.
- add-on therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control

\*\*\*Confidential information removed\*\*\*

### Draft Remit

To appraise the clinical and cost effectiveness of dulaglutide within its marketing authorisation for treating type 2 diabetes.

### Main points from consultation

Following the consultation exercise, NICE is of the opinion that an appraisal of dulaglutide for treating type 2 diabetes is **not appropriate**.

There is already clear and effective guidance on use of GLP-1 mimetics in NICE guideline 28. Therefore the company believes that appraisals of dulaglutide (and semaglutide – also being considered for referral in this batch) should not be considered a priority given that these are the 6th and 7th drugs in the class and do not have a price premium over most GLP-1 mimetics. A clinical guideline update would be of more value, incorporating the positive effects of all GLP-1 mimetics on cardiovascular risk and in renal dysfunction (the most important new data to emerge for this class), once fully available. A professional group also highlighted emerging cardiovascular outcomes data for dulaglutide and expressed concern that, currently, NICE would be reviewing incomplete information.

If NICE decides to proceed with a technology appraisal for semaglutide, Eli Lilly would wish NICE to proceed with a technology appraisal for dulaglutide in parallel i.e. the outcome of the scoping process should be consistent for both drugs.

A comparator company (of a SGLT2 inhibitor) believes it would only be appropriate to refer this topic for appraisal if it is an MTA that includes SGLT2 inhibitors and other GLP-1 mimetics as interventions, incorporating cardiovascular outcomes data. This stakeholder is concerned that proceeding with an STA could exclude potentially relevant information and impact guidelines unethically, resulting in patients not receiving the appropriate medication for their individualised management needs.

## Population Size

Over 3 million people in England could be eligible for treatment with semaglutide because there were over 3.1 million people in England with diagnosed type 2 diabetes mellitus in 2017.

**Process (TA/HST):** N/A – referral not sought. Topic to be incorporated in clinical guideline update.

## Proposed changes to remit

N/A – referral not sought

## Costing implications

The list price of dulaglutide is around £70 for 4 pre-filled disposable injections, this results in an annual cost of around £950 per person. However, potential uptake of dulaglutide is unknown and therefore the resource impact is unknown.

## Timeliness Statement

N/A – referral not sought.