NHS
Devon
Clinical Commissioning Group

Clinical Policy Engagement & Consultation Panel

MINUTES

Thursday 23 July 2020, 14.00-15.00

Via teleconference

Present:

Nicola Bonas	Deputy Head of Communications
Charlotte Burrows*	Governing Body Lay Member for patient & public involvement
Rebecca Heayn	Clinical Effectiveness Governance Manager
Carol McCormack-Hole*	Lay Member from the Patient Engagement Forum
Mac Merrett*	Lay Public Member, Clinical Policy Committee
Chris Roome	Head of Clinical Effectiveness
Jon Taylor	Strategy Manager
Mark Taylor*	Lay Public Member, Clinical Policy Committee

* Denotes voting members

1. Welcome and Introductions

The group were welcomed and thanked for joining the meeting via Microsoft Teams.

2. Declaration of Interests

No specific interests pertinent to the items for discussion on the meeting agenda were declared.

3. Minutes from the meeting 4 June 2020

The panel considered the minutes from the meeting held on 4 June 2020 and agreed them to be an accurate record.

The action log was updated as follows:

Action no.	Description and update
20/01	Annual report to be reported to the CCG for information and assurance. **Rebecca Heayn advised that the Annual Report had been received by the Clinical Policy Committee at their meeting on 1 July 2020 and is due to be submitted to the Commissioning Committee for assurance.**

4. Discussion and recommendation on the Clinical Policy Committee decisions from 1 July 2020

Prasterone (Intrarosa®) for the treatment of vulvar and vaginal atrophy

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel.

The decline in oestrogen in postmenopausal women results in a decrease in vaginal lubrication, an early symptom of vulvovaginal atrophy. Management of vulvovaginal atrophy is usually with moisturisers, lubricants and topical oestrogens.

Prasterone is a precursor steroid to oestrogens and androgens. It is a vaginal pessary which is administered once a day. It had been considered by the Clinical Policy Committee following an application from a consultant obstetrician and gynaecologist from Royal Devon and Exeter NHS Foundation Trust.

The panel considered the public interest themes in relation to this policy:

1. Is the reason for introducing the policy plausible? and 2. Does the policy output address this intent?

   It was noted that an application had been received for the use of prasterone to be supported in Devon as an additional treatment option for women with vulvar and vaginal atrophy who do not get adequate symptom relief from other treatments. After consideration, the Clinical Policy Committee has not recommended the routine commissioning of prasterone in Devon for the treatment of vulvar and vaginal atrophy as there is no evidence to support efficacy in those who have not obtained relief from other steroid treatments and it is not considered to represent good value to the local health economy.

3. Have the effects of the policy on individual patients and carers been considered?

   It was acknowledged that the consultant applicant had anticipated the use of prasterone to be in a small number of patients only, as most respond to the existing treatment options available. These comprise moisturisers, lubricants and topical oestrogens. The committee had noted that there is no evidence that patients who have failed topical vaginal oestrogens will respond to prasterone.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy beyond the individuals involved.

5. Has the opportunity cost been considered?

   It was noted that prasterone is £125 more expensive annually per patient than existing treatment options, and the committee concluded that the evidence did not support a significant clinical benefit to justify this extra financial cost.

   It had also been discussed that most patients with vulvovaginal atrophy are treated in general practice rather than by specialists. The committee therefore felt that the potential number of patients would be larger than the consultant had estimated. The possible restriction of prasterone to specialist use would likely result in an increase in referrals with questionable benefit.

6. Is there knowledge of public concern in relation to a) the disease and b) the specific intervention?

   The panel were not aware of any specific public concern in respect of vulvar and vaginal atrophy. However there was discussion as to whether this is a common but hidden condition, perhaps due to there being a stigma associated with it. It was

questioned whether there is a cohort of patients who may be untreated as a result of it being a condition which is not well enough known. It was considered that there are a number of simple treatments which patients can try themselves, as described by nhs.uk; if these do not work other treatment options are accessible via their GP.

7. What information on the treatment and condition is available to patients via nhs.uk (formerly NHS Choices)?

   nhs.uk gives information on symptoms, causes and treatments of vaginal dryness. It notes that there are a number of things that a woman can try themselves, most of which are available from a pharmacy without a prescription.

   It is stated to see a GP if the things that a patient is trying themselves are not working, it's affecting their daily life, they have unusual discharge or bleeding, or have bleeding after sex or in between periods.

   If the vaginal dryness is because of changes in hormone levels, it is stated that a patient may be prescribed creams, gels, patches or medicines to increase a hormone called oestrogen (hormone replacement therapy).

   Prasterone is not specifically mentioned as a treatment option.

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point.

Ospemifene (Senshio®) for the treatment of vulvar and vaginal atrophy

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel.

This was another option for the treatment of vulvovaginal atrophy which had been considered by the Clinical Policy Committee following an application from a consultant obstetrician and gynaecologist from Torbay and South Devon NHS Foundation Trust. Management of vulvovaginal atrophy is usually with moisturisers, lubricants and topical oestrogens.

Ospemifene is a selective oestrogen receptor modulator. It is an oral tablet taken once a day. Unlike oestrogen containing topical treatments, ospemifene is suitable for patients with a history of breast cancer who are no longer undergoing active treatment, or who have recovered from sex-hormone dependent cancer.

The panel considered the public interest themes in relation to this policy:

1. Is the reason for introducing the policy plausible? and 2. Does the policy output address this intent?

   It was noted that an application had been received for the use of ospemifene to be supported in Devon as treatment option for women with vulvar and vaginal atrophy. After consideration, the Clinical Policy Committee has not recommended the routine commissioning of ospemifene in Devon for the treatment of vulvar and vaginal atrophy as they considered it did not offer a sufficiently large improvement in symptoms over the use of moisturisers and lubricants alone.

3. Have the effects of the policy on individual patients and carers been considered?

   It was acknowledged that ospemifene is suitable for patients who are no longer undergoing active treatment for breast cancer, including adjunctive treatment such as tamoxifen, or who have recovered from sex-hormone dependent cancer. However the committee had concluded that the magnitude of benefit of ospemifene

over existing moisturisers and lubricants was small given the cost and it was therefore not considered to be good value for money.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy beyond the individuals involved.

5. Has the opportunity cost been considered?

   It was noted that ospemifene costs £515 annually per patient and is substantially more expense than existing treatment options. The committee considered that ospemifene did not offer a sufficiently large improvement in symptoms over the use of moisturisers and lubricants alone and therefore it is not considered to represent good value for the local health economy.

6. Is there knowledge of public concern in relation to a) the disease and b) the specific intervention?

   As per the previous discussion of prasterone, the panel were not aware of any specific public concern in respect of vulvar and vaginal atrophy. However there was discussion as to whether this is a common but hidden condition, and whether there is a cohort of patients who may be untreated. It was considered that there are a number of simple treatments which patients can try themselves, as described on nhs.uk; if these do not work other treatment options are accessible via their GP.

7. What information on the treatment and condition is available to patients via nhs.uk (formerly NHS Choices)?

   nhs.uk gives information on symptoms, causes and treatments of vaginal dryness. It notes that there are a number of things that a woman can try themselves, most of which are available from a pharmacy without a prescription.

   It is stated to see a GP if the things that a patient is trying themselves are not working, it's affecting their daily life, they have unusual discharge or bleeding, or have bleeding after sex or in between periods.

   It the vaginal dryness is because of changes in hormone levels, it is stated that a patient may be prescribed creams, gels, patches or medicines to increase a hormone called oestrogen (hormone replacement therapy).

   Ospemifene is not specifically mentioned as a treatment option.

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point.

5. Any Other Business

No other business was raised.

6. Next meeting date

The next meeting is due to be held on Thursday 24 September 2020 from 2.00pm.