NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Appraisal consultation document

Slow-release potassium bicarbonate–potassium citrate for treating distal renal tubular acidosis

The Department of Health and Social Care has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using slow-release potassium bicarbonate and potassium citrate in the NHS in England. The appraisal committee has considered the evidence submitted by the company and the views of non-company consultees and commentators, clinical experts, and patient experts.

This document has been prepared for consultation with the consultees. It summarises the evidence and views that have been considered and sets out the recommendations made by the committee. NICE invites comments from the consultees and commentators for this appraisal and the public. This document should be read along with the evidence (see the committee papers).

The appraisal committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

Issue date: June 2022

Note that this document is not NICE's final guidance on this technology. The recommendations in section 1 may change after consultation.

After consultation:

- The appraisal committee will meet again to consider the evidence, this appraisal consultation document and comments from the consultees.
- At that meeting, the committee will also consider comments made by people who are not consultees.
- After considering these comments, the committee will prepare the final appraisal document.
- Subject to any appeal by consultees, the final appraisal document may be used as the basis for NICE's guidance on using slow-release potassium bicarbonate and potassium citrate in the NHS in England.

For further details, see NICE's guide to the processes of technology appraisal.

The key dates for this appraisal are:

Closing date for comments: 12 July 2022

Second appraisal committee meeting: 4 August 2022

- Details of membership of the appraisal committee are given in section 5

1 Recommendations

1.1 Slow-release potassium bicarbonate–potassium citrate is not recommended, within its marketing authorisation, for treating distal renal tubular acidosis in people 1 year and over.

1.2 This recommendation is not intended to affect treatment with slow-release potassium bicarbonate–potassium citrate that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop. For children and young people, this decision should be made jointly by them, their clinician, and their parents or carers.

Why the committee made these recommendations

Standard care for distal renal tubular acidosis is alkalinising therapy used outside its UK marketing authorisation.

The clinical trials of slow-release potassium bicarbonate–potassium citrate were short, small, not done in the UK and provided no head-to-head data, so the results are highly uncertain. Because of this uncertainty, it is not possible to tell whether slow-release potassium bicarbonate–potassium citrate is more effective than standard care.

There are also limitations with the economic model including issues with its structure and the sources of evidence used to inform it. Because of these limitations and the uncertainty in the clinical evidence, the cost-effectiveness estimates are uncertain. Also, the most likely estimates are much higher than what NICE usually considers an acceptable use of NHS resources. So, slow-release potassium bicarbonate–potassium citrate is not recommended.

2 Information about slow-release potassium bicarbonate and potassium citrate

Marketing authorisation indication

2.1 Slow-release potassium bicarbonate–potassium citrate (Sibnayal, Advicenne) is indicated for 'the treatment of distal renal tubular acidosis (dRTA) in adults, adolescents and children aged one year and older.'

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for slow-release potassium bicarbonate–potassium citrate.

Price

2.3 The company's list price is £360.00 per pack of 60 sachets of 24 milliequivalent (mEq) prolonged-release granules or £120.00 per pack of 60 sachets of 8 mEq prolonged-release granules (company submission, excluding VAT). The company has a commercial arrangement (simple discount PAS), which would have applied if the technology had been recommended.

3 Committee discussion

The appraisal committee considered evidence submitted by Advicenne, a review of this submission by the evidence review group (ERG), and responses from stakeholders. See the committee papers for full details of the evidence.

The committee was aware that some issues were resolved after technical engagement. It recognised that there were remaining areas of uncertainty and took these into account in its decision making.

The condition

Distal renal tubular acidosis significantly affects quality of life

3.1 Distal renal tubular acidosis (dRTA) is a disease of impaired acid removal from the blood. This causes the blood to become too acidic. There are 2 types of dRTA: hereditary or acquired. Hereditary dRTA, also known as primary dRTA, is inherited from a person's parents, and is often diagnosed at a young age. Some people with inherited dRTA have no accompanying symptoms while others may have kidney stones, deafness, growth failure, rickets (bowing of the bones) or osteoporosis (thinning of the bones). Acquired dRTA, also known as secondary dRTA, can develop during a person's lifetime because of other conditions like Sjögren syndrome, sickle cell anaemia, systemic lupus erythematosus, chronic obstructive uropathy, or post-renal transplantation. Common symptoms for adults with dRTA include muscle weakness, paralysis, problems with the kidneys, osteomalacia (softening of the bones), polydipsia (feeling thirsty despite drinking enough fluid), polyuria (excessive urination), and rickets. The patient expert's statement explained that dRTA has significant impact on their mental health, family life, occupation and dietary intake. The clinical expert further stated that dRTA is a rare condition which can significantly affect quality of life and disrupt normal daily activities. The committee concluded that there is a significant effect on quality of life and disruption of normal daily activities for people with dRTA.

Treatment pathway and comparator

There is an unmet need for treatment for dRTA

3.2 Management of dRTA is with alkalinising therapy, used outside its UK marketing authorisation, to correct the levels of acid in the blood to the normal range. Restoring adequate metabolic control is key to lowering the risk and development of long-term and life-threatening outcomes of dRTA. Alkalinising therapies are short-acting and are taken multiple times a day. The company stated that taking alkalinising replacement therapy is a

burden on people's quality of life because they have to wake up during the night to take the treatment. The clinical expert explained that the timing of medication could be adjusted to ensure that treatment is limited to the daytime unless there was a specific reason. The patient expert's statement explained that it is a struggle to take treatment 3 times a day and people have to adjust it to ensure good control. The committee concluded that there is an unmet need for treatment for dRTA.

Standard care is an appropriate comparator

3.3 Standard care in the UK is alkalinising therapy. The company defined standard care based on the range and percentage of alkali treatments used in its clinical trial. The treatments used in the trial were: 8.1% had potassium bicarbonate; 21.7% had potassium citrate; 2.7% had modified Shohl's solution (citric acid and hydrous sodium citrate); 18.9% had sodium bicarbonate; 8.1% had a combination of potassium bicarbonate and potassium citrate; 13.5% had a combination of potassium bicarbonate and sodium bicarbonate; 24.3% had a combination of potassium citrate and sodium bicarbonate and 2.7% had a combination of modified Shohl's solution and sodium bicarbonate. The clinical expert thought it was likely that the company's breakdown of standard care matched clinical practice. However, they noted that doses and timings are individualised to fit with people's lives, so it is hard to generalise. The committee concluded that the company's standard care is an appropriate comparator.

Clinical effectiveness evidence

B21CS and B22CS had small patient numbers, did not include head-to-head data and were done over a short period of time

3.4 The company's key clinical evidence for slow-release potassium bicarbonate–potassium citrate came from the B21CS and B22CS studies. B21CS was a multicentre, open label, non-inferiority study with a follow up of up to 40 days. People had standard care for 5 days, then had a titration period of up to 30 days to determine the dose of slow-release potassium

bicarbonate–potassium citrate that worked best for each person (also known as optimal dose). After the titration period, people would have a maximum of 5 days on the optimal dose. The trial was done in France, Serbia and Slovakia. B21CS enrolled people with an established diagnosis of dRTA with metabolic acidosis. The trial used a staggered approach to enrol people into 4 age subsets (18 years and over, 12 to 17 years, 4 to 11 years, and 6 months to 3 years), with a minimum of 4 people in each subset. B21CS compared slow-release potassium bicarbonate–potassium citrate with alkalinising therapy which was defined as standard care. Because dRTA does not have a directly measurable end point, a surrogate outcome of average blood bicarbonate level was used in the trial to assess outcomes. The clinical experts agreed that this was an appropriate surrogate outcome. The B21CS intention-to-treat analysis included 37 people but only 30 people completed the trial as per the protocol. B22CS was a single-arm, multicentre, open label, 24-month extension study to B21CS to assess the safety of slow-release potassium bicarbonate–potassium citrate. The trial was originally planned for 24 months but was extended for an additional 6 months in some countries. B22CS included 30 people with inherited dRTA who had completed study B21CS. For B22CS the primary end point was the number or proportion of people experiencing adverse events during the course of the study, including the incidence and severity of adverse events. The clinical expert explained that although the trials were not done in the UK, standard care in the trial was likely to be representative of UK current practice. The committee concluded that B21CS and B22CS have small patient numbers, did not include head-to-head data, and were done over a short period of time.

It is unclear if slow-release potassium bicarbonate–potassium citrate has a benefit over standard care

3.5 B21CS compared people's mean blood bicarbonate level during the 5 days on standard care with their mean blood bicarbonate level during

their 5 days of optimal slow-release potassium bicarbonate–potassium citrate. It showed that people had a mean blood bicarbonate level of 21.7 millimoles per litre (mmol/L) (standard deviation [SD], 3.06 mmol/L) when they had standard care compared with 23.1 mmol/L (SD, 1.62 mmol/L) when they had slow-release potassium bicarbonate–potassium citrate. Mean difference was 1.42 mmol/L (95% confidence interval, 0.4128 to 2.4263). The extension safety study, B22CS, showed that from month 3 to month 48, the percentage of people with blood bicarbonate levels in the normal range was between 60.9% and 91.3%. Adverse events were experienced by 90% of people but most of these were of mild or moderate intensity. The committee recalled that there were considerable uncertainties associated with the efficacy of slow-release potassium bicarbonate–potassium citrate because of limitations including:

- low patient numbers in both studies
- people's blood bicarbonate levels on standard care and slow-release potassium bicarbonate–potassium citrate were compared meaning they act as their own control in B21CS
- people only had optimal slow-release potassium bicarbonate–potassium citrate treatment for a maximum of 5 days in B21CS
- B22CS was a single-arm trial with a maximum duration of 48 months.
- efficacy measurements in the trial are surrogate end points for which meaningful levels of improvement and connection to long-term therapeutic benefit is unclear
- efficacy of standard care in the model is based on relative efficacy between slow-release potassium bicarbonate–potassium citrate and standard care in B21CS. There is no data for standard care beyond the initial 5 days so the long-term relative effect is uncertain.

The ERG explained that in the model the efficacy of slow-release potassium bicarbonate–potassium citrate and standard care is

extrapolated up to 75 years but the company had not provided any additional evidence to support this long-term efficacy. The clinical expert explained that because the trial was a non-inferiority trial it is hard to conclude anything about a potential benefit of slow-release potassium bicarbonate–potassium citrate over standard care. The committee was aware of a lack of comparative evidence and long-term outcomes. They also noted it is difficult to know if the mean difference from the trial is clinically meaningful because of the short time period of treatment in B21CS. The company suggested that it may have more data at 48 months of the trial but that there is no new evidence or trials planned. The committee concluded that it is unclear if slow-release potassium bicarbonate–potassium citrate has a benefit over standard care.

Economic model

There are multiple limitations with the functionality and concepts in the company's model

3.6 The company's model was a state transition model. People move through the model based on their disease response to treatment and if they experience nephrocalcinosis, nephrolithiasis, stage 2 to 4 chronic kidney disease, end stage kidney disease, or kidney transplant. The ERG identified multiple conceptualisation and functionality issues with the company's model. The company's state transition model allowed people to move between health states when their disease progressed or response to treatment changed. However, the ERG explained that there were some key limitations with how people move through the model. Three issues with the model structure were:

- people whose disease responds to either slow-release potassium bicarbonate–potassium citrate or standard care cannot progress beyond chronic kidney disease stage 2 (CKD2)

- people whose disease does not respond, but they remain on either slow-release potassium bicarbonate–potassium citrate or standard care, cannot progress to end stage kidney disease
- people stopping treatment will never restart either slow-release potassium bicarbonate–potassium citrate or standard care.

Clinical advice to the ERG suggested that although it is rare for people to move between these states, it can happen. Therefore, this should be possible in the model. The clinical expert also agreed that people do move between these health states. The company did not provide any justification for why the model does not include these transitions. Another limitation of the model is that people whose disease control is lost or regained will not move health states. Therefore, differences in health and costs between having controlled disease and uncontrolled disease are not accounted for. The ERG explained that people should never change disease state (that is, lose or regain disease control) within 1 health state. Instead, they should be modelled as 2 separate health states. The ERG also highlighted that conditions such as osteomalacia or rickets are chronic in nature but have been modelled as transitory health states. This means that the long-term health effects of these chronic conditions cannot be accounted for. The ERG explained that it assumed no quality adjusted life year (QALY) loss because of this, which is a conservative approach. The committee concluded that there are multiple limitations with the functionality and the concepts in the company's economic model.

There is considerable reliance on clinical opinion in the model and this introduces uncertainty

3.7 The model assumptions rely mainly on expert clinical opinion rather than trial data or evidence from the literature. It is not clear how much the clinical estimates that were used to populate the model influence the model results. The key parameters that rely on clinical opinion are the transition probabilities and discontinuation rates. These parameters are a driver of the QALY benefit in the model. The company explained that it

used a modified Delphi process and that it did everything it could, to maximise reliability of the inputs. The ERG recognised that the 2 targeted literature reviews done by the company to identify model parameters were systematic, pragmatic, and transparent. The ERG explained that the company should have provided reasons for choosing the sources used to populate the model. The committee concluded that there is considerable reliance on clinical opinion because of the lack of data and that introduces uncertainty.

People with acquired dRTA could not be included in the model because of the lack of data

3.8 The company included people with acquired dRTA and people with inherited dRTA in the model. Acquired forms of dRTA are usually associated with autoimmune diseases, such as Sjögren's syndrome, systemic lupus erythematosus or autoimmune chronic liver disease. The company assumed that 1 in 7 people with dRTA had acquired dRTA based on B21CS. Because acquired dRTA is associated with these autoimmune diseases, the company applied a utility decrement of 0.18 to people with acquired dRTA in the model. However, it assumed people with controlled disease would not experience this utility decrement. The ERG explained that the company did not provide any evidence to show why these diseases would have no impact on people who have controlled dRTA disease. The ERG also highlighted that the utility decrement of 0.18 was taken from a study about renal replacement therapy for acute renal failure at a Finnish tertiary centre. The ERG explained that only 1 person in B21CS had acquired dRTA and that this person did not continue on to B22CS. This means there is no long-term data for people with acquired dRTA. Therefore, given the limitations, the ERG provided incremental cost-effectiveness ratios (ICERs) for inherited dRTA only and explained that if acquired dRTA is a distinct subgroup it should be analysed separately. The committee concluded that people with acquired dRTA could not be included in the model because of the lack of data.

The most appropriate definition of disease control is uncertain

3.9 In the model, the company defined controlled disease at the start of the model, as normal mean blood bicarbonate levels across days 2 to 4. However, in the B21CS trial, controlled disease was defined as normal blood bicarbonate levels on all of days 2 to 4. The ERG explained that the company choice of definition in the model is not justified. If the 2 different definitions are used, there would be different proportions of people with disease control at the start of the model. Using the company's model definition 90% of people taking slow-release potassium bicarbonate–potassium citrate have controlled disease at the start of the model and 43.33% of people taking standard care have controlled disease. Using the B21CS definition, 76.67% of people taking slow-release potassium bicarbonate–potassium citrate and 36.67% of people taking standard care have controlled disease at the start of the model. The ERG also explained a definition of controlled disease based on the people used to calculate the transition probabilities in the model. Using this definition, the proportion of people taking slow-release potassium bicarbonate–potassium citrate at the start of the model would be 63.33% and for people taking standard care, 44.33%. The transition probabilities-based definition and the company model definition appear inconsistent with the B21CS trial. The committee concluded that the most appropriate definition of controlled disease is uncertain.

Assuming that disease control is the same regardless of age in the company's model is uncertain

3.10 The company's model assumes the probability of maintaining or recovering disease control is independent of age. This assumption was supported by clinical advice received by the ERG, but the data for people having slow-release potassium bicarbonate–potassium citrate in B22CS suggested that a difference in disease control based on age could be plausible. However, the ERG noted that B22CS had a small sample size which may introduce uncertainty. The ERG maintained the company's

assumption of equal disease control regardless of age but highlighted that the assumption is subject to uncertainty. The committee concluded that assuming disease control is the same regardless of age is uncertain.

The company's original utility multiplier for end stage kidney disease is appropriate

3.11 The company used utility multipliers for different health states in the model. A utility multiplier is used to multiply a person's baseline utility in the model to give their utility while in the health state. The company updated its utility multipliers during technical engagement to match the sources preferred by the ERG. The committee noted a face validity error with the multiplier for end stage kidney disease. The multiplier for end stage kidney disease was 0.809 but this was higher than the utility multiplier of 0.619 for kidney transplants. The clinical expert explained they would expect a larger drop in utility from end stage kidney disease than from kidney transplant. Therefore, the utility multiplier for end stage kidney disease should be lower than for kidney transplant. The company's original utility for end stage kidney disease was 0.541. The ERG agreed that there was a face validity error so accepted the company's original lower utility multiplier. The committee concluded that the company's original end stage kidney disease utility multiplier of 0.541 was most appropriate.

A utility decrement should be applied to standard care because of the inconvenient dosing, but a decrement of 0.04 is uncertain

3.12 The company explained that because treatments used in standard care are short-acting, 86.5% of people take 3 to 6 doses per day. This causes sleep disturbance in about 27% of people because the doses must be evenly spread throughout the day and night. The company explained that children's doses are often given during the night because this is when they actively grow so their dRTA needs to be controlled. The clinical expert explained that in the UK, standard care would not be given at night

unless necessary. This is because children's growth at night is not usually considered an issue or measured by UK clinicians. They explained that in the UK, clinicians try to adjust the timing of medication to match the person's needs. The clinical expert also stated that they try to achieve disease control with as few doses of standard care as possible. Slow-release potassium bicarbonate–potassium citrate is taken twice a day, 12 hours apart which means that people do not experience sleep disturbance. The clinical expert noted that slow-release potassium bicarbonate–potassium citrate is provided in a sachet. This gives more flexibility for people when they are away from home particularly if they are traveling, because standard care is often provided as a solution. They also explained that because the number of doses of slow-release potassium bicarbonate–potassium citrate is fewer than standard care, it would have a positive effect on people's quality of life and would improve adherence to treatment. Consequently, this may reduce the need to monitor people's blood bicarbonate levels. B22CS collected visual analogue scale scores to assess if slow-release potassium bicarbonate–potassium citrate is more convenient to take. Most people in B22CS thought that slow-release potassium bicarbonate–potassium citrate was a more appropriate formulation, had a more convenient number of doses and had a better taste than standard care. Because of this, the company added a utility decrement for people taking standard care to account for the inconvenience of taking it. The company did a targeted literature review because there was no direct utility data captured in either B21CS or B22CS. It chose a utility decrement of 0.04 based on a study investigating the burden associated with taking frequent oral medication in people with Gaucher disease. The ERG explained that none of the studies identified in the literature review were ideal but agreed that 0.04 was reasonable. The committee concluded that a utility decrement should be applied to standard care because of the benefits of slow-release potassium bicarbonate–potassium citrate administration and that 0.04 is reasonable although uncertain.

The QALY gain and additional cost of slow-release potassium bicarbonate–potassium citrate seen in the model are not justified

3.13 The company's model predicts a QALY gain associated with slow-release potassium bicarbonate–potassium citrate over standard care. The exact numbers are confidential and cannot be reported here. The committee noted that this QALY gain was not supported by the clinical evidence presented by the company so questioned what was causing it. The ERG explained that it is caused by:

- a large number of people discontinuing treatment with standard care in the model which means they progress to end stage kidney disease faster and have lower QALYs in that health state
- model limitations that people cannot move through chronic kidney disease stages when they are treated so a large number of people on potassium bicarbonate–potassium citrate do not move to health states with lower QALYs
- the efficacy between potassium bicarbonate–potassium citrate and standard care being fixed which means people on standard care will only do half as well as those on potassium bicarbonate–potassium citrate
- better formulation, better taste and better dosing schedule of slow-release potassium bicarbonate–potassium citrate which increases people's quality of life.

The committee recalled the benefits of slow-release potassium bicarbonate–potassium citrate on mental health, family life, work and managing diet but concluded the QALY gain was not justified. The committee also questioned the increased cost of slow-release potassium bicarbonate–potassium citrate compared with standard care. They questioned why potassium bicarbonate–potassium citrate was more expensive than the cost of potassium bicarbonate and potassium citrate separately. The company explained that per milliequivalent (mEq), the cost of slow-release potassium bicarbonate–potassium citrate is not much

greater than standard care. The exact numbers are commercial in confidence and cannot be reported here. The ERG explained that the dosage varies between standard care and slow-release potassium bicarbonate–potassium citrate which could be driving the higher cost in the model. They also explained that there are high discontinuation rates in the model for people on standard care meaning the lifetime cost for standard care is low. The ERG added that it is not certain about the robustness of the model results. The committee noted that the reasons given by the ERG were speculative and that they would like to see further cost breakdowns. The committee concluded that there is not sufficient justification for the increased QALYs and costs of slow-release potassium bicarbonate–potassium citrate.

Cost-effectiveness estimates

The cost-effectiveness estimates are highly uncertain and are higher than what NICE considers a cost-effective use of resources

3.14 NICE's guide to the methods of technology appraisal notes that above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of a technology as an effective use of NHS resources will take into account the degree of certainty around the ICER. It also notes that the committee will be more cautious about recommending a technology if it is less certain about the ICERs presented.

Because of confidential commercial arrangements for Shohl's solution, potassium bicarbonate and sodium bicarbonate (all standard care treatments), the ICERs are confidential and cannot be reported here. The committee noted that neither the company's nor the ERG's base case met its preferences of:

- having no people with acquired dRTA in the model (section 3.8)
- a utility multiplier of 0.541 for end stage kidney disease (ESKD) (section 3.11)

- a utility decrement of 0.04 applied to standard care (section 3.12).

The committee noted the high level of uncertainty, specifically because of:

- no comparative efficacy data for slow-release potassium bicarbonate–potassium citrate compared with standard care (section 3.5)
- limitations in the functionality and concepts in the model, including:
  - people whose disease responds to treatment cannot progress beyond CKD2
  - people whose disease does not respond, but they remain on treatment, cannot progress to ESKD
  - people discontinuing treatment will never restart treatment
  - people whose disease loses control or regains control remain in the same health state
  - conditions that are chronic in nature have been modelled as transitory health states (section 3.6)
- reliance on clinical opinion for a substantial proportion of model parameters (section 3.7)
- assumption that disease control is the same for people regardless of age (section 3.10)
- the definition used for disease control (section 3.9)
- the QALY and cost gain in the model (section 3.12).

Considering all confidential discounts and using the committee's preferred assumptions, the cost-effectiveness estimates generated exceeded what NICE would consider a cost-effective use of resources.

Conclusion

Slow-release potassium bicarbonate–potassium citrate is not recommended for use in the NHS and alternative modelling techniques should be considered

3.15 The committee considered the functionality and model concepts limitations of the model (see section 3.6) and the implausible QALYs and costs. They also noted that the ICERs were above the threshold NICE considers a cost-effective use of NHS resources. Therefore, the committee did not recommend slow-release potassium bicarbonate–potassium citrate for use in the NHS. However, since there is a lot of uncertainty in the model, the committee agreed that a cost-comparison approach, that assumes the similar efficacy of slow-release potassium bicarbonate–potassium citrate and standard care, might be an alternative option to using a cost-utility approach. The committee also noted that given the implausible cost and QALY outcomes, the time horizon could be significantly shortened as well as reducing percentage adherence over time.

Innovation

Slow-release potassium bicarbonate–potassium citrate has a more convenient dosing regimen and this is reflected in the cost-effectiveness estimates

3.16 The company considered slow-release potassium bicarbonate–potassium citrate to be innovative because it addresses a significant unmet need for the treatment of dRTA. It is the first treatment for dRTA with a marketing authorisation. Current standard care is a less convenient dosing regimen than slow-release potassium bicarbonate–potassium citrate, which can place a burden on people's quality of life. The committee acknowledged the new benefits offered by slow-release potassium bicarbonate–

potassium citrate. However, it concluded that these benefits had been captured in the economic model.

Equality

Increased adherence is accounted for in the economic model, but more evidence is needed for people with acquired dRTA

3.17 During scoping it was raised that black people are less likely to seek and follow medical advice for dRTA. The committee considered the more convenient dosing regimen of slow-release potassium bicarbonate–potassium (see section 3.12). They concluded that the more convenient dosing regimen and increased adherence was accounted for in the economic model. It was also raised that some people with acquired dRTA have other conditions and therefore could have an increased risk of fractures. The ERG explained that fractures were included in the model as a transitory health state. However, committee recalled the lack of data for acquired dRTA (see section 3.8) which meant it could not be included in the model. The committee concluded that they would need to see more evidence for acquired dRTA to fully consider this equality issue.

4 Proposed date for review of guidance

4.1 NICE proposes that the guidance on this technology is considered for review 3 years after publication of the guidance. NICE welcomes comment on this proposed date. NICE will decide whether the technology should be reviewed based on information gathered by NICE, and in consultation with consultees and commentators.

Megan John
Chair, appraisal committee
May 2022

5 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee D.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

Haider Shamsi and Sarah Wilkes
Technical lead

Caron Jones and Sally Doss
Technical adviser

Celia Mayers
Project manager

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