NICE National Institute for Health and Care Excellence

Sodium zirconium cyclosilicate for treating hyperkalaemia [ID1293]

Consultation on the appraisal consultation document – deadline for comments 5pm on 19/11/2018 **email:** TACommB@nice.org.uk/NICE DOCS

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. 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 provisional recommendations sound and a suitable basis for guidance to the NHS? NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the preliminary recommendations may need changing in order to meet these aims. In particular, please tell us if the preliminary recommendations: • could have a different impact on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology; • could have any adverse impact on people with a particular disability or disabilities. Please provide any relevant information or data you have regarding such impacts and how they could be avoided or reduced**.**
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	[Renal Association]
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	[**No new disclosures from last submission**] Was present as expert at NICE Meeting during review of drugs – therefore heard all comments during the open meeting
Name of commentator person completing form:	[Prof Sunil Bhandari]

Comment number	**Comments** Insert each comment in a new row.

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	Do not paste other tables into this table, because your comments could get lost – type directly into this table.
Example 1	We are concerned that this recommendation may imply that ……..
1	We are concerned that by not approving these novel treatments, at least with restrictions, this will limit optimal patient care and restrict clinicians from treating a cohort of patients with difficult to control potassium values, leading to premature dialysis, serious morbidity, unnecessary hospitalisation and possible mortality.
2	We feel that the new potassium binders have a role in facilitating safer use of renin angiotensin blockers (ie ACE inhibitors (ACE-I) or Angiotensin receptor blockers (ARB)) in some patients with CKD and/or cardiac failure. These agents are proven to be of definite clinical benefit in both conditions but can lead to hyperkalaemia; clinicians would choose to use potassium binders at [potassium] > 5.5 mmol/l to prevent [potassium] reaching 6 mmol/l and above . In both patient groups there are many occasions where renin angiotensin blockade has to be reduced or terminated due to hyperkalaemia, leading to increased patient risk.
3	We are concerned that there may have been some misunderstanding concerning the nature of patients suitable for treatment with the new potassium binders. These agents are not intended for acute management of patients with [potassium] > 6 mmol/l. However, they would provide treatment options, together with dietary restriction, that are currently not available after acute treatment of hyperkalaemia in order to prevent recurrent hyperkalaemia and to facilitate safer use of ACE-I and ARB, necessary treatments for patients with CKD and/or heart failure.
4	We feel that the NICE panel should recognise the importance of the many recurrent and unnecessary hospitalisations that are associated with hyperkalaemia in patients with CKD and/or heart failure. These are associated with major cost, morbidity and mortality. The new potassium binders appear to have the capacity to reduce this burden.
5	Calcium resonium has been available as a potassium binder for decades but most patients suffer gastrointestinal side effects; intestinal necrosis is a very serious but rare complication. We feel that NICE should recommend the use of the novel potassium binders as an alternative for calcium resonium therapy, which remains in guidelines.
6	In summary, we would like to see the NICE panel consider permitting use of the new potassium binders for restricted use and prescription by clinicians managing patients with CKD and/or heart failure in a secondary care setting. It is important that this therapeutic option gains real world experience in the UK such that clinicians can establish the use of these agents in a group of patients with multiple comorbidities and limited quality of life until further data becomes available to extend their use to other groups of patients.

Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 set of comments from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Please underline all confidential information, and separately highlight information that is submitted under 'commercial in confidence' in turquoise and all information submitted under 'academic in confidence' in yellow. If confidential information is submitted, please also send a 2nd version of your comment with that information replaced with the following text: 'academic / commercial in confidence information removed'. See the Guide to the processes of technology appraisal (section 3.1.23 to 3.1.29) for more information.
- Do not include medical information about yourself or another person from which you or

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the person could be identified.

- Do not use abbreviations
- Do not include attachments such as research articles, letters or leaflets. For copyright reasons, we will have to return comments forms that have attachments without reading them. You can resubmit your comments form without attachments, it must send it by the deadline.
- If you have received agreement from NICE to submit additional evidence with your comments on the appraisal consultation document, please submit these separately.

Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory committees.