AstraZeneca – Call for Grant Applications (CGA CKD-SGLT2 2001)

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Applications may be submitted until March 1, 2021, with start dates of October 1, 2020 or later. Review may be on a rolling basis</th>
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<td>Primary Area of Focus</td>
<td>Nephrology</td>
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<td>Therapeutic Area</td>
<td>Chronic Kidney Disease – SGLT2 Inhibition</td>
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| Educational Format | • Accredited medical education programs designed to address knowledge and competence gaps to improve clinical care  
  • Examples include satellite symposium with enduring activities, regional/hospital series, and online activities |
| Educational Audience | Primary: Nephrology and Primary Care  
  Secondary: Cardiology, Endocrinology, Internal Medicine; (physicians, physician assistants, nurse practitioners, nurses, pharmacy) |
| Program Cost | ≤ $225,000.00 |
| Successful submission | • Independently-developed application, providing rationale (educational and practice gaps) and detailed description of the goals, learning objectives, format, execution and measurement of program  
  • Program design including multiple non-didactic formats to enhance knowledge transfer, retention, and translation to practice (e.g., panel discussions; case-based) |
| CGA Code | CGA CKD-SGLT2 2001 |

Chronic kidney disease (CKD) is highly prevalent in the United States, affecting an estimated 37 million people.¹ There can be various causes and underlying etiology, with a high burden due to diabetes, and also non-diabetic causes such as hypertension and glomerulonephropathies.²,³ In addition, CKD is a known independent risk factor for cardiovascular disease. In the FDA-mandated post-marketing cardiovascular safety trials for new diabetes medications, the sodium-glucose co-transporter 2 (SGLT2) inhibitors demonstrated beneficial effects on cardiovascular, heart failure and renal outcomes in patients with type 2 diabetes across a spectrum of cardiovascular risk.⁴⁻⁷ However, the majority of patients enrolled had an estimated glomerular filtration rate (eGFR) above 60 mL/min/1.73 m² with normoalbuminuria, thus the effects of SGLT2 inhibition on renal outcomes in patients with more advanced renal disease required further study.⁸ Subsequently, a renal outcomes study with an SGLT2 inhibitor has shown benefits on renal and cardiovascular outcomes in patients with type 2 diabetes and proteinuric CKD.⁹ Observations suggest the mechanisms for the benefits of SGLT2 inhibition on renal outcomes are independent of glycemic status and effects on plasma glucose. Emerging evidence with SGLT2 inhibitors suggest the observed renal benefits may be maintained in patients without type 2 diabetes. Further studies are evaluating the effects of SGLT2 inhibitors in CKD patients with and without diabetes. Given this, healthcare professionals who manage patients with chronic kidney disease could benefit from evidence-based education on:

- The burden of CKD and existing unmet needs in the management of residual renal, CV, and mortality risk, despite optimal standard-of-care
- The observed effects of SGLT-2 inhibition on the onset and progression of CKD in patients with type 2 diabetes from recent large outcomes trials
- The clinical evidence to support the use of SGLT-2 inhibition in the management of progressive renal decline and/or proteinuria in CKD patients without type 2 diabetes
- The safety profile of SGLT-2 inhibitors in patients with impaired renal function
- The recommended dosage and administration of SGLT-2 inhibitors based on eGFR
- The potential mechanisms of renal benefit of SGLT-2 inhibition beyond glycemic control and the complement to RAAS inhibition, including rationale for beneficial effects in patients with non-diabetic CKD

• The considerations for the potential role of SGLT-2 inhibitors in patients with renal impairment and the appropriate implementation in evidence-based management of CKD

Successful applications will include the rationale (educational and practice gaps) and a detailed description of the education goals, learning objectives, format, execution, and measurement of the program. The program design should include multiple non-didactic formats to enhance knowledge transfer, retention, and translation to practice. There should be measurement of Level 4 / 5 outcomes, including sub-analyses by audience characteristics.

References:


Program Requirements:

The Program must be planned and executed as if an accredited activity and fully compliant with the criteria and/or standards of commercial support for ACCME, AAFP, AOA, ACPE, ANCC, AANP, or NCCPA. Furthermore, the program will be educational and non-promotional in nature and will be planned, designed and implemented in accordance with the U.S. Food and Drug Administration’s Guidance on Industry-Supported Scientific and Educational Activities ("Policy Statement").

The Policy Statement and the ACCME Standards require, among other things, that (i) Institution conduct the Program independently and without control or influence by AstraZeneca over the Program's planning, content (including the selection of speakers or moderators), or execution; (ii) the Program be free of commercial bias for or against any product; (iii) Institution make meaningful disclosure of AstraZeneca support of the Program and any prior relationship between Institution and AstraZeneca, and the relationship, if any, between AstraZeneca and the speakers selected by Institution; and (iv) AstraZeneca not engage in, and Institution not permit any other sponsor to engage in, promotional activities in or near the Program room or advertise its products in any materials disseminated as part of the Program.

In addition, Institution is required by the Policy Statement and, if applicable, accreditation standards to ensure that any product discussions at the Program be accurate, objective, balanced and scientifically rigorous. This includes a balanced discussion of each product and of treatment alternatives, that limitations on data be disclosed, that unapproved uses be identified as such, and that for live presentations there be opportunities for questioning or debate.