Request for Proposal (RFP) for Quality Improvement Educational Initiative

Improving the Identification of Risk Factors and Prevention of Venous Thromboembolism in Multiple Myeloma Patients
Purpose of RFP

The Scientific Education department of Celgene Corporation is seeking proposals to address the following identified quality and education gaps through quality improvement methodology. The purpose of the RFP is to improve physicians’ ability to identify and assess multiple myeloma patients at risk for venous thromboembolism (VTE) and ensure these patients receive adequate prophylaxis and treatment per guideline recommendations.

Applicant Eligibility

Applicants must be US-based and in good standing and accredited by an official accrediting agency (e.g., ACCME, ANCC, ACPE). Applicants must have demonstrated experience in executing quality improvement programs.

Grantee Expectations

Each applicant must select an evidence-based or innovative intervention to address the quality and education gaps identified. Applicants are expected to:

- Develop an well-conceived, evidence-based implementation plan
- Provide a budget necessary to implement the project successfully
- Evaluate the impact of the initiative
- Provide a plan to sustain the program beyond the initial funding

Timeline

Submission Deadline: October 27, 2014 at 5PM EST
Notification by end of November 2014
### Disease State/Therapeutic Area: Multiple Myeloma/Hematology

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<th>Clinical Gap and Balanced Educational Gap</th>
<th>Requested Educational Audience and Educational Format</th>
<th>Alignment to NQA Priorities</th>
<th>Quality Driven Endpoint for Consideration</th>
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<td>Venous thromboembolism (VTE) is a serious complication in patients, representing a $500-million burden on the health care system in the United States. Despite several guidelines for the prevention and treatment of cancer-related thrombosis, many oncology patients do not receive appropriate VTE prophylaxis and treatment. Data from a registry suggests that only 45% of 1735 patients with cancer received thromboprophylaxis which is not consistent with the ACCP guidelines. Myeloma has a high risk of venous thromboembolism (VTE). The incidence of VTE and arterial thromboembolism in MM patients ranges between 3% and 10%, depending on the presence of specific risk factors. Recent evidence suggests that VTE can negatively affect survival in multiple myeloma patients; prevention of VTE may therefore positively influence prognosis. Patient-related risk factors.11</td>
<td>Celgene is seeking to support a quality improvement education initiative focused on improving the healthcare teams’ ability to identify and assess multiple myeloma patients at risk for VTE and ensure these patients receive adequate prophylaxis and treatment per guideline recommendations. Consideration will be given to ideas that include but may not be limited to care coordination, team based designs, patient engagement approaches and others to identify risk factors and determine appropriate prophylaxis. The ultimate goal is to provide evidence that shows an improvement in patient safety and care. Given the magnitude of the problem and how care is provided to multiple myeloma patients, preference will be given to well conceived projects that include commitment from healthcare groups and systems as collaborators. Projects in closed-systems such as an integrated delivery network, ACO or hospital are preferred and please outline the selection criteria used for the system.</td>
<td>• <strong>Patient Safety</strong>: Making care safer by reducing harm caused in the delivery of care + <strong>Coordination of Care</strong>: Promoting effective communication and coordination of care + <strong>Dissemination of Best Practices</strong>: Promoting the most effective prevention and treatment practices for the leading causes of mortality + <strong>Patient and Caregiver Engagement</strong>: Ensuring that each person and family are engaged as partners in their care</td>
<td>This initiative should aim to provide results that align with the ASCO Practice Guideline: “Venous Thromboembolism Prophylaxis and Treatment in Patients with Cancer” with a focus on: • Patients with multiple myeloma receiving antiangiogenesis agents with chemotherapy and/or dexamethasone should receive prophylaxis with either low–molecular weight heparin (LMWH) or low-dose aspirin. And the International Myeloma Working Group Consensus Statement: “Management of Myeloma Patients not Eligible for Standard Autologous Stem-cell Transplantation” with a focus on: • MM patients should receive an appropriate thromboprophylaxis with a risk-stratified approach for the first 4–6 months of treatment, until disease control is achieved or as long as the risk of thromboembolism remains high. And the American College of Chest Physicians Guidelines with a focus on: • Recommend LMWH or low-dose unfractionated heparin in outpatients with tumors and additional risk factors for VTE, including thalidomide and lenalidomide therapy. And the NCCN Guidelines V1.2014 with a focus on:</td>
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<td>Factors include advanced age, history of VTE or inherited thrombophilia, obesity, co-morbidities, central venous catheter in situ, immobility and surgery. Myeloma-related factors include the diagnosis of myeloma itself, disease burden and hyperviscosity. Treatment-related factors include the use of thalidomide or lenalidomide particularly when combined with high-dose steroids or doxorubicin or multi-agent chemotherapy, and concomitant use of erythropoietin.6,7,8 This information highlights the need for increased education on the burden of VTE and appropriate management for patients with multiple myeloma.</td>
<td>The proposal should include an assessment of the current practice using identified evidence-based quality performance measures, implementation plan of intervention(s), and re-evaluation of performance measures to gauge improvement in quality. This may include both short-term and long-term process and outcome measures. Based on external research, Celgene believes this quality improvement education initiative is best suited for multidisciplinary healthcare teams within a hematologists and/or oncologists practice.</td>
<td>- Multiple myeloma patients receiving thalidomide or lenalidomide in combination with high-dose dexamethasone or doxorubicin or multi-agent chemotherapy or for myeloma patients with 2 or more individual or myeloma risk factors, recommended prophylaxis is LMWH or warfarin.13</td>
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Terms and Conditions

1. Applications received in response to this RFP will be reviewed in accordance with Celgene Corporation’s policies and standards.

2. This RFP does not commit Celgene Corporation to award a grant or to pay any costs incurred in the preparation of a response to this request.

3. Celgene Corporation reserves the right to approve or deny any or all applications received as a result of this request or to cancel, in part or in its entirety, this RFP.

4. Those who choose to submit to this RFP must follow the submission instructions below. Failure to comply will automatically disqualify your submission.

Submission Instructions

Celgene Corporation reserves the right to modify this RFP at any time and reserves the right to reject any and all responses to this RFP, in whole or in part, at any time. Celgene Corporation, at its sole discretion, has the right to disclose the details of funded projects, including those that may be required by federal, state, and/or local laws and regulations. This disclosure may include, but shall not be limited to, details of the activity and the grant amount.
Submission Requirements for a Quality Improvement Project

Proposals should be structured based on below format to ensure standardization and evaluation of all responses. All the sections listed below must be included in the proposal, in the order presented, with the Section Number listed. The responses shall be submitted in the following format:

Section 1 Justification and Need for QI Project- This section must include a well-referenced gap analysis that demonstrates the specific QI and Educational gaps and barriers of the intended target audience or healthcare organization(s)/system. Additionally, information about how the needs were identified must be presented. Use “real-world” or primary data from various sources to justify need for project is desired including any supporting baseline data. Reference data sources in Section 7.

Section 2- Quality Improvement Project- Components of the Project should include:

   a) Leadership and Organizational Support for Proposed QI interventions. The key to the success of the Continuous Quality Improvement process is leadership. Describes how the leaders of your organization and/or partnering organizations provide support to quality improvement interventions. Provide a letter of support from key partners as part of your submission.

   b) Proposed QI Project:
      i) Activities should be base from QI theories and frameworks.
      ii) Clearly define the population, measures and indicators, and rationale for the intervention design. Proposals should outline how the interventions will be developed, by whom, and the methods to ensure complete, accurate and evidence-based information.
      iii) Clearly describe how your program or its components to the priorities outlined under National Quality Strategy (http://www.ahrq.gov/workingforquality/about.htm).
      iv) Measurement and Analysis- describe specifically the approach, methodology, measurement design, statistical analysis, and reporting. Please include how you plan to calculate measures and what data sources will be used to support the measurement of your project. The specific measurement plan should specify anticipated outcomes in terms of improved patient safety/quality or patient care and a plan if the target/goal cannot be or is not achieved.
      v) Sustainability. Please describe how you intend to sustain your QI project beyond the initial funding.
      vi) Timeline of activities and milestones. Please provide a detailed timeline and milestone of your program. The timeline should indicate the proposed start and end dates.

Section 3. Budget- This section should included a detailed budget with rationale including breakdown of costs associated with management of the program, content development and out-of-pockets.

Section 4. Organizational Profile- This section should provide a brief overview of your organization, past experience, and pertinent information to delivery of QI programming. In
addition, describe your program including the organizational mission and vision, the types of services provided, organizational structure and profile.

Section 5. Partnerships- Provide a list of partners and their roles in the proposed QI project. A letter of support is desired.

Section 6. Communication Plan- Describe in detail your plans to publish and disseminate project findings.

Section 7. Accreditation- Programs must be accredited by the appropriate accrediting bodies and fully compliant with all ACCME criteria and Standards for Commercial Support. If you are a non-accredited provider, the accredited provider must be involved from the concept origin, fully knowledgeable of the grant submission and documentation should be provided.

Section 8. Resolution of Conflict- This section should describe methods for ensuring fair and balanced content, and identification and resolution of conflict of interest.

Section 9 Appendices. Any additional and relevant information should be attached as an appendix.

References

4. Zonder J, Schiffer CA. UpToDate, March 6, 2012
