United States Senate WASHINGTON, DC 20510

July 20, 2011

The Honorable Donald M. Berwick, MD Administrator Centers for Medicare & Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue SW, Room 314G Washington, DC 20201

Dear Administrator Berwick:

This letter, along with the enclosed supporting documentation, is a formal request for a National Coverage Determination (NCD) for the use of Avastin to treat age-related macular degeneration (AMD) in the Medicare population. We believe that, given new evidence cited below, a CMS review will lead to an affirmative coverage policy that ensures Medicare beneficiaries diagnosed with AMD have access to Avastin in addition to Lucentis, as an option for treatment.

As you know, age-related macular degeneration can cause blindness in elderly individuals. As a result of recent breakthrough drugs, a diagnosis of AMD no longer necessarily means blindness or permanent vision impairment. Since its approval by FDA in 2006, the biologic drug Lucentis has provided many seniors with the ability to preserve their sight as they grow older.

However, according to many eye specialists and now the National Institutes of Health (NIH), Lucentis is not the only effective treatment for wet AMD. Another similar biologic, Avastin, used in small packaged amounts for intraocular purposes, has also been used to treat wet AMD at significantly lower cost to patients and Medicare. Avastin costs as little as five percent as much as Lucentis' price of \$2,000 per dose.

A recently-released NIH sponsored multi-year comparative clinical trial (the "CATT" trial) has concluded that both drugs are similarly efficacious and safe in treating these serious eye-related ailments. We believe this evidence strongly supports CMS issuing a national coverage policy that ensures that Medicare beneficiaries with AMD have access to Avastin as well as Lucentis, and we urge you to carefully review the results of this trial. We expect that CMS—like many ophthalmologists already have—will find that Avastin is a safe, reasonable, and necessary treatment for AMD.

By issuing a positive NCD for Avastin, more affordable access to AMD treatment will become widely available to Medicare beneficiaries. In addition to this increased access to an effective treatment for blindness, the American taxpayer will also benefit due to savings in Medicare spending.

We thank you for your consideration in this matter and respectfully ask for your immediate attention to the issue. We look forward to the beginning of the NCD process. Should you need additional information on this matter, please feel free to contact Jack Mitchell of Senator Kohl's staff at 202-224-5364.

Sincerely,

Herb Kohl

U.S. Senator U.S. Senat