Medicare 2012-2017 Intravitreal Injections: Certification and Credentials of Providers

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OBJECTIVE To describe the medical degree, subspecialty, and certification of providers of intravitreal injections in the US.

PURPOSE Intravitreal injection is the most common ophthalmic procedure worldwide and is rapidly growing in utilization. In the US, intravitreal injections are commonly administered by retina specialists, as they have the highest level of training to perform these procedures, and manage any potential complications. However, increased treatment burden is leading some states to consider alternate providers.

METHODS Calendar year 2017 Centers for Medicare and Medicaid Services (CMS) data were culled for number of intravitreal injection services, and the provider's medical specialty and degree. The American Board of Ophthalmology (ABO) website was used to determine board certification status for each provider. Retina subspecialty was determined for each provider using the American Society of Retina Specialists (ASRS) current and historical membership list, or report of a completed retina fellowship on the provider's clinic website. A physician was defined as a medical doctor (MD) or doctor of osteopathy (DO).

RESULTS For 2017, CMS reported a total of 3,102,033 intravitreal injections, including aflibercept (40%), bevacizumab (26%), ranibizumab (21%), triamcinolone (4%), and dexamethasone (1%). Board certified ophthalmologists administered 96% of the injections and retina specialists administered 92% of the injections. Non-ophthalmologists accounted for 0.13% of the injections, and rare non-physicians (2 nurse practitioners, and 3 physician assistants) accounted for 0.016% of the intravitreal injections.

CONCLUSION Although some states permit intravitreal injection by non-physicians, the

standard of care in the US remains administration of intravitreal injection by an ophthalmologist with ABO board certification and subspecialty training in retina. Data are lacking regarding the safety and outcomes of intravitreal injection by non-physicians and other providers without this certification and training.

HUMAN RESEARCH No: Study does not involve human research

Modifier-25 Examinations Reduce Travel Burden, Decrease Treatment Cost, and Improve QALY for Exudative Age-Related Macular Degeneration Patients

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OBJECTIVE To compare the costs of different treatment paradigms for neovascular age related macular degeneration (wAMD) in common use in the United States.

PURPOSE Intravitreal injection is the most common surgical ophthalmologic procedure worldwide, increasing in frequency each year. In the US, most intravitreal injections are performed on the same day as an office examination; however, federal agencies and insurance payers suggest that same-day (modifier-25) examination charges are over-utilized and have recommended scrutiny of these charges. In this study, we estimate the cost vs. benefit to society of same day office visits during intravitreal injections for wet age-related macular degeneration (wAMD).

METHODS An Excel spreadsheet was created to model different anti-VEGF treatment scenarios for wAMD. Treatment parameters for intravitreal injections, office examinations, and OCT testing payments were estimated using US population statistics, published literature, and CMS provider utilization data. Costs and benefits were compared for 3 established treatment scenarios: A) continuous anti-VEGF therapy (10.1 injections, 1.9 office examinations per year), B) office-based treat and extend (T&E) anti-VEGF therapy (5.8 injections, 5.8 same-day office visits per year) , and C) anti-VEGF therapy in an injection clinic (8.6 injections, 4.7 same-day office visits per year). Monitoring of fellow-eye AMD was considered in this analysis, but other ophthalmologic and systemic diseases were not.

RESULTS Although office examinations and OCT costs were higher for T&E ($858) and

injection clinic ($497) protocols vs. continuous treatment ($280), our model predicts reduced yearly treatment costs for T&E ($6,858) and injection clinic ($10,131) vs. continuous treatment ($11,860) due to decreased pharmaceutical expenses afforded by less frequent treatment. Also, travel and chaperone costs were reduced for T&E ($536) and injection clinic ($672) vs. continuous treatment ($942). For the US population, we calculate a cost savings of $7.2 billion (T&E protocol) and $2.7 billion (injection clinic) annually, as compared to continuous therapy. Furthermore, early detection of wAMD in the fellow eye during same-day office examinations allows for a 2.1 and 1.8 QALY benefit per patient in the T&E and injection clinic cohorts, respectively, as compared to the continuous treatment arm, with a favorable $5,402 and $2,891 cost per QALY, respectively.

CONCLUSION Modifier-25 same-day examinations during anti-VEGF therapy for wAMD reduce treatment and travel costs, and improve screening of the fellow eye, resulting in robust cost savings and QALY benefit for the US population.

HUMAN RESEARCH Yes: Exempt from approval

Opioid Prescribing Patterns and Trends of American Society of Retina Specialists (ASRS) Members

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OBJECTIVE To describe the opioid prescribing patterns and trends of ASRS members in the United States.

PURPOSE The use of opioids in the United States has grown considerably. Increases in opioid-related deaths and complications have prompted clinicians in all fields to scrutinize their prescribing patterns. We sought to determine the opioid prescribing patterns among retina specialists.

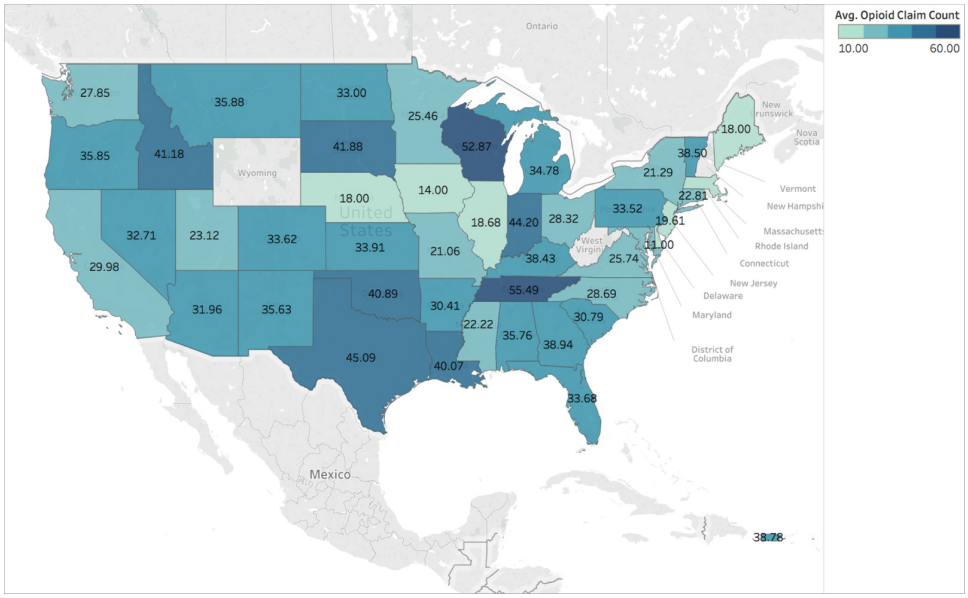
METHODS An observational, retrospective, cohort study was conducted of American Society of Retina Specialists (ASRS) members' prescribing patterns in the 2013-2016 Medicare Part D Prescriber database. ASRS members within the United States were profiled from the ASRS member directory as of April 2019. The Centers for Medicare and Medicaid Services Medicare Part D Prescriber Public Use Files for 2013, 2014, 2015, and 2016 were accessed. Data were collected and analyzed regarding the prescribing patterns for opioid drugs for all participating ASRS members. The mean number of opioid prescriptions written annually by retina specialists, prescriber rates compared with all prescriptions written, and geographic distribution of opioid prescriptions written per retina specialist were analyzed.

RESULTS 1,815 retina specialists were identified in the 2019 ASRS directory. Members had written a total of 15,610 prescriptions in 2016 with 70% of members writing at least 1 opioid prescription. On average, members wrote 11 opioid prescriptions per year. Almost a quarter (24%) wrote >10 prescriptions annually. A minority wrote >50 prescriptions per year (5%). Among those writing >10 prescriptions annually, 16 opioid prescriptions were given annually with a mean supply of 4 days. Using multivariable analysis, the factors associated with increased number of opioid prescriptions were male gender ($\beta = 3.86$, $P < 0.001$) and a practice location in the South ($\beta = 5.61$, $P < 0.001$). The total number of opioid

prescriptions including refills written by members also decreased by 18% from 2013 to 2016 (P<0.001).

CONCLUSION ASRS members prescribed opioids at a rate (3%) lower than the national mean of all prescribers (6.8%). Male gender and a practice location in the South were correlated to number of prescriptions. The present opioid abuse epidemic should prompt physicians to reconsider their prescribing protocols given the high risk for dependency.

HUMAN RESEARCH No: Study does not involve human research



Geographic Distribution of Opioid Prescriptions Written Annually per Physician

Physician Quality Outcome Measures Don’t Reliably Measure Quality for Individual Ophthalmologists

- John T. Thompson, MD

OBJECTIVE To evaluate limitations in the current Medicare outcome quality measures for ophthalmology

PURPOSE This study evaluated the reliability of current outcome quality measures for ophthalmology by evaluating expected differences between higher versus lower performing ophthalmologists.

METHODS All 29 Medicare Merit-based Incentive Payment System (MIPS) clinical quality outcome measures for ophthalmology were evaluated by modeling expected differences between potential typical performance.

RESULTS Medicare uses MIPS to reward perceived high-quality ophthalmologists with bonuses in reimbursement. Medicare has been eliminating previously accepted process measures such as recommending AREDS supplements or communicating with the primary care physician in favor of outcome measures. There are substantial limitations in the way the current outcome measures are applied to individual physicians due to small sample sizes, small differences in clinical outcomes and lack of risk adjustments. 26/29 ophthalmology outcome measures have no established benchmarks as of 2019 reporting period. Medicare requires a minimum of 20 cases performed in the first 9 months of the calendar year to be counted for measures with a 90-day look-back. Many retina specialists would not achieve the 20-case minimum based on typical surgical volumes for epiretinal membrane and macular hole measures making it more difficult to report on the required 6 measures. A comparison of surgeon A who has 25 eligible cases with epiretinal membranes or macular holes and no returns to the OR within 90 days versus surgeon B who has 5 of 25 patients requiring a return to the OR would have a p value of 0.0502. Medicare assigns quality points between 3 and 10 based on dividing the difference between the best and worst performances into deciles. There is no significant difference between surgeon A and

B, yet surgeon A would be rewarded for better performance. The small sample size problem is ameliorated when larger sample sizes are obtained, but for procedures such as cataract surgery with high success rates, the difference between the better and poorer performance rates may still not be significant. A comparison of surgeon C who performs 250 cataract surgeries with no complications requiring a return to the OR within 30 days versus surgeon D who has 5 of 250 cataract patients with complications requiring a return to the OR would have a p value of 0.0722. Similar comparisons for most outcome measures with small sample sizes or small expected differences between better and poorer performing ophthalmologists show a lack of statistical significance. Further complicating these attempts to measure quality is a lack of risk adjustment for ophthalmologists who have a higher proportion of patients who are economically disadvantaged or who are referred more complicated cases. Errors in capturing the clinical results accurately from the electronic health record systems to Medicare compound this problem.

CONCLUSION It is difficult to identify outcomes measures that reliably distinguish between good and poor performing ophthalmologists. The current MIPS system and future public reporting of physician scores for outcome measures is based on flawed methodology.

HUMAN RESEARCH No: Study does not involve human research

Cost of Initial Aflibercept, Laser, or Observation in Eyes With Diabetic Macular Edema and Good Vision Based on Management Approaches in Protocol V

- Jennifer K. Sun, MD

OBJECTIVE What are estimated US population costs with the DRCR.net Protocol V strategies of initial aflibercept, laser or observation for eyes with center-involved diabetic macular edema and good visual acuity?

PURPOSE To estimate the overall US population costs over a 10-year horizon, using Protocol V strategies of initial aflibercept, laser or observation to manage eyes with center-involved diabetic macular edema (DME) and good visual acuity (VA). Given similar VA outcomes at 2 years, understanding estimated population costs of these strategies may be relevant for health care planning.

METHODS Adults with DME (confirmed on OCT) and good VA (Snellen equivalent 20/25 or better) in the study eye were randomly assigned to initial management with aflibercept, laser, or observation (DRCR Retina Network Protocol V). Aflibercept was given in the laser and observation groups if VA met pre-specified worsening criteria during follow-up. The prevalence and incidence of center-involved DME and good VA were estimated based on prior studies. Costs were estimated for the US population from 2020-2029, applying the Protocol V observed visit and treatment frequency over the first two years within each group, while varying the number of injections and visits in the third and following years of therapy

RESULTS Among 702 randomized participants (mean age 59 years; 264 (38%) female); the percentage of eyes with a ≥ 5-letter VA decrease at 2 years (primary outcome) was 16%, 17%, and 19% in the aflibercept, laser photocoagulation, and observation groups, respectively. In the laser photocoagulation and observation groups, aflibercept was initiated in 25% and 34% of eyes. Over 2 years the average number of visits was 17.8, 12.4, and 13.5 in the aflibercept, laser, and observation groups, respectively; with an average of 8.3, 2.1, and 3.1 aflibercept injections. Not unexpectedly, this analysis demonstrates that initial

management with aflibercept is more expensive for an individual participant and from a societal perspective over a 10-year horizon than initial management with either laser or observation. Initial management with observation may be more expensive than initial management with laser over a 10-year horizon.

CONCLUSION These estimates for the US population over a 10 year horizon suggest that initial laser or observation strategies may offer substantial cost savings compared to immediate aflibercept treatment as used in Protocol V for eyes with DME and good VA.

HUMAN RESEARCH Yes: Approved by institutional review board

Analysis of Emergent Non-Hospital Based Retina Consultation Requests in an Academic Non-Hospital Associated Retina Practice

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OBJECTIVE What are the outcomes of after-hours appointment requests for patients with acute complaints?

PURPOSE The purpose of this study is to evaluate the outcomes of after-hour encounters concerning patients referred by eye physicians or self-referred to on-call retina services for emergent evaluation not seen in or referred by an emergency department.

METHODS A retrospective chart review was conducted composing of all patients who presented emergently and after clinic hours to three academic non-hospital associated retina-only private practice institutions over a two-year period.

RESULTS A total of 987 charts were reviewed. The mean age was 60 and 48% of the patients were male. New patients accounted for 53% of all visits. The most common presenting symptoms were flashes and floaters (42.55%). The majority of symptom duration was one day or less (39.41%) followed by two days or less (17.22%). The most common diagnoses given at the appointment were posterior vitreous detachment (15.20%), macula on retinal detachment (9.93%), macula off retinal detachment (9.73%), retinal tear (9.52%) and vitreous hemorrhage (8.81%). An in-office procedure was performed at the time of exam in 18% of encounters with the majority of these being laser retinopexy. Surgery was performed within 24 hours (18%), within 48 hours (21%), within 72 hours (22%), and within 96 hours (23%) of the appointment. In total, 23% of encounters led to surgery within 96 hours. When combined with procedures, 36% of encounters led to urgent intervention within 24 hours.

CONCLUSION This study supports the need for hospital independent on-call retina services to support the local eye care community and supplement hospital-based eye institutions. When viewed as a whole, after hours appointment requests have a high likelihood (36%) of needing an intervention within 96 hours, with the majority of those needing intervention within 24 hours of the appointment.

HUMAN RESEARCH Yes: Approved by institutional review board