July 16, 2020

Wendy MacLeod, MD
National Medical Director
UnitedHealthcare
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Re: Catheter Ablation for Atrial Fibrillation Prior Authorization

Dear Dr. MacLeod:

The American College of Cardiology (ACC) and the Heart Rhythm Society (HRS) are urgently advising UnitedHealthcare to suspend its implementation of prior authorization rules for Catheter Ablation for Atrial Fibrillation effective July 1, 2020 due to: 1) concerns on the adverse impact on and access to the care of our patients; 2) misconceptions on the implications of randomized clinical trials in atrial fibrillation (AF) and utilization of atrial fibrillation ablation; 3) misconceptions on the indications for atrial fibrillation ablation, including excluding potential patient benefits, such as improved quality of life; 4) concerns with the MCG™ Care Guidelines, 24th edition, 2020, Electrophysiologic Study and Intracardiac Catheter Ablation ORG: M-154 (ISC).

ACC and HRS are in alignment with UHC with the need to ensure that care is appropriate, timely, and necessary. Cardiology leads all specialties in the development of guidelines, consensus statements, and appropriate use criteria. Atrial fibrillation ablation has been an established procedure in defined patient populations for over two decades and has positively impacted the lives of millions of patients around the world, who suffer from this debilitating rhythm disorder. We have reviewed your letter and the justification in support of your proposed process. In reviewing the rationale behind your decision, we would like to rectify several inaccurate interpretations of the scientific data that appear to form the basis for your policy.

Impact of atrial fibrillation on the lives of patients
We are concerned that there is a fundamental misunderstanding regarding the impact that atrial fibrillation has on the lives of patients. The present coverage decision does not seem to take this into account. Patients with atrial fibrillation have significantly poorer quality of life compared to healthy controls, the general population, and patients with other cardiovascular disease.[1, 2] Although stroke prevention is an important goal of AF treatment, minimizing

symptoms, physical limitations, and the negative impact AF has on quality-of-life is tantamount for patients. Recent data has also highlighted the strong link between AF burden and the development on heart failure over time[3, 4], another highly morbid condition. Although AF is associated with increased mortality, the absolute risk elevation of death in contemporary populations is low as evidenced by CABANA and other trials; thus, mortality reduction is not the primary goal of therapy. The goal is to improve quality of life and prevent the subsequent development of comorbidities, such as heart failure, stroke, and dementia, that might eventually over time result in death.

Impact of AF Ablation on Quality of Life

Several studies support the significant positive impact of atrial fibrillation ablation on quality of life, as measured by a number of indices.[5-9] The CABANA study, a randomized clinical trial of catheter ablation vs. drug therapy in 2204 patients with atrial fibrillation, was the largest and demonstrated clinically important and significant improvements in quality of life favoring catheter ablation over drug therapy.[5] These results have contributed to the favoring of atrial fibrillation ablation by patients. Patient organizations, such as StopAfib.org, Afibbers.org, a-fib.com, and arrhythmiaalliance.org.uk, have websites that include many patient testimonials as to the benefits of atrial fibrillation ablation and its impact on quality of life (https://www.stopafib.org/stories.cfm).

Utilization of the ablation procedure for atrial fibrillation

Your June 12, 2020 letter stated that "*UnitedHealthcare evaluates utilization trends for many clinical procedures. We noted a 21% increase in utilization for catheter ablation for AFib in our 2018-2019 trend data. The rate of use of this procedure has been escalating despite the results of the CABANA trial in 2018, which found that the procedure was no more effective than medications at reducing mortality, cardiac arrest, major bleeding and stroke.*"

We appreciate your concerns about possible atrial fibrillation ablation overutilization. However, the assumption that the increase in atrial fibrillation ablations is a result of overutilization is a misrepresentation. The incidence of atrial fibrillation in the United States is doubling from 1.2 to 2.6 million and prevalence from 5.2 million to 12.1 million by 2030.[10] The ballooning incidence and prevalence of atrial fibrillation is fed by the epidemic of obesity and the increasing age of the population.[11-13] Thus, in the United States, as citizens live longer and have more associated risk factors, we are seeing much more atrial fibrillation. As a result, there is inherently more demand for atrial fibrillation ablation. When atrial fibrillation ablation became mainstream in the late 1990s, the number of physicians and institutions that could offer this procedure was very small. Today, atrial fibrillation ablation is a mature therapy and technological advancements have resulted in significant improvements in procedure-related complications and efficacy. Such incremental advances have resulted in the adoption of atrial fibrillation ablation as an important therapeutic strategy by physicians and embraced by patients, moving it from a therapy of last resort for drug-refractory, highly symptomatic atrial fibrillation to first line therapy.[14-16] The CABANA trial and other randomized trials of atrial fibrillation ablation compared to medical therapy have definitively demonstrated that atrial

fibrillation burden is markedly reduced by atrial fibrillation ablation compared with drug therapy.[14-18] This reduction in atrial fibrillation burden and the demonstrated improvements in quality of life[5-9] after atrial fibrillation ablation that are superior to what can be achieved with only medical management contributes to the higher demand by patients for atrial fibrillation ablation.

Prior authorization and burden on health systems and physicians

Prior authorization processes have added a tremendous burden to healthcare delivery and significantly impacted access to care and patient satisfaction. Adding yet another onerous prior authorization process to an already overburdened health care system has many flaws. Perhaps the most important consideration is that prior authorization adversely affects health outcomes.[13] For example, restrictive policies requiring prior authorization for clopidogrel usage after percutaneous coronary intervention (PCI) with stenting[19] and PCSK9 inhibitors[20] have been associated with poor patient outcomes. Elimination of such process has significantly improved access to appropriate therapy and improved cardiovascular outcomes.[19, 21] Arduous pre-authorization processes deny timely access to beneficial therapy for at risk patients, whose life is burdened by the disease. Higher rejection rates for PCSK9 inhibitors were observed with women, racial minorities, and lower income groups and were related to higher cardiovascular outcome rates.[20] This situation could be analogous to atrial fibrillation catheter ablation, as CABANA demonstrated racial minorities is a subgroup that significantly benefited from atrial fibrillation ablation compared to medical therapy in the primary endpoint of death, disabling stroke, serious bleeding, or cardiac arrest.[22] Efforts focused on only minimizing costs without consideration of the overall improvement in health outcomes and the quality of life for a patient is inconsistent with optimal disease management and ethical principles.[23] Instituting these pre-authorization processes during the COVID-19 pandemic, when hospitals and physicians practices are struggling with inadequate resources to provide care, makes the adoption of this prior authorization requirement, particularly one that delays care for 15 days, even more onerous. Such lengthy processing times will delay patient care and increase the administrative burdens for clinical staff

Professional Societal guidelines for AF ablation:

The consensus guidelines from all the major cardiology and electrophysiology societies clearly define the role of atrial fibrillation ablation as an important tool for symptom mitigation.[15] Like many other medical interventions, atrial fibrillation ablation is not performed to reduce mortality. While there is evidence that atrial fibrillation ablation might indeed reduce mortality in certain subgroups of the population, the primary reason that we perform atrial fibrillation ablation is to improve the quality of our patients lives. The alternatives to atrial fibrillation ablation have substantial limitations related to inferior symptom control, significant side effects, increased need for hospitalization, and lower effectiveness in maintaining sinus rhythm and preventing atrial fibrillation recurrence.[15] While atrial fibrillation ablation is often used in symptomatic patients after failing one or more antiarrhythmic drugs, there is clear evidence that it is an excellent first line therapy.[15, 16] The societal guidelines and current clinical evidence supports this approach.

CABANA Trial – differences in interpretation

In your June 12, 2020 letter, it was stated that "*The rate of use of this procedure has been escalating despite the results of the CABANA trial in 2018, which found that the procedure was no more effective than medications at reducing mortality, cardiac arrest, major bleeding and stroke."*

We respectfully disagree with the limited interpretation of the CABANA data by your team. While we recognize the mortality, bleeding and stroke outcomes of the CABANA trial,[22] we are concerned that UnitedHealthcare has disregarded the other important outcomes of CABANA and numerous other randomized studies of atrial fibrillation catheter ablation that show superior long-term quality of life (QoL) and symptomatic relief from catheter ablation compared to medical therapies.[5-9] The *2017 HRS Expert Consensus Statement on Catheter and Surgical Ablation*[15]also states "the primary clinical benefit from catheter ablation of AF is an improvement in quality of life resulting from elimination of arrhythmia-related symptoms, such as palpitations, fatigue, or effort intolerance." Indeed, the indication for ablation in many patients is for symptom improvement, not mortality reduction. The 2017 Consensus Statement[15] continues, summarizing three prospective randomized clinical trials that have examined the relative efficacy and safety of first-line AF ablation vs pharmacological therapy. These findings provide evidence to support the role of AF ablation as first-line therapy.

As noted above, in a subsequent publication on quality of life observed in the CABANA randomized trial, compared with medical therapy, ablation led to superior clinically important and significant improvements in quality of life.[5] These findings can help guide decision-making in the management of atrial fibrillation.[5] Furthermore, in a recent Journal of the American College of Cardiology (JACC) article, catheter ablation was effective in reducing recurrence of any AF by 48% and symptomatic AF by 51% compared with drug therapy over 5 years of follow-up in the CABANA Trial.[14] Based on this primary quality of life benefit, the safety of the procedure, and recent medical literature, we would anticipate the CABANA results to positively impact the clinical practice of care and patient-clinician decision to utilize catheter ablation.

Other important outcomes measured by CABANA included death or cardiovascular hospitalizations, which was 17% lower in the catheter ablation compared to the drug therapy group (hazard ratio [HR] 0.83, 95% confidence interval [CI] 0.74-0.93, p=0.001).[22] Moreover, significant superiority of catheter ablation over drug therapy in the primary endpoint composite of death, disabling stroke, serious bleeding, or cardiac arrest was found in patients who were younger <age 65 (HR 0.52, 95% CI 0.27-1.00) and patients in minority populations (HR 0.43, 95% CI 0.20-0.95). Limiting access to these populations would perpetuate significant healthcare disparities.

Significant benefits of catheter ablation over medical therapy for patients with heart failure were observed in the randomized CASTLE-AF trial.[18] Similar findings with strong trends favoring catheter ablation in heart failure patients were also observed in CABANA.[22] Limiting or delaying

AF ablation in this at risk population due to delays in prior authorization procedures could be deleterious to the patients.

It is also noteworthy that there was significant cross over (30%) from the anti-arrhythmic drug arm to the ablation arm in CABANA due to therapy failure, and 10% of the ablation arm never received the ablation therapy.[22] When analyzed from an 'as-treated' perspective, there was a clear reduction in death, stroke, serious bleeding, or arrest with catheter ablation (HR 0.73, 95% CI 0.54-0.99, p = 0.046). While intention to treat (ITT) analyses represent the ideal, they often differ from on treatment analyses. Real life experience with medical interventions are often closer to on-treatment than intention-treat analyses. While we completely understand the validity of the ITT approach, one must be cautious, when using this data to establish coverage decisions, when factors such as high cross over rates and less than optimal intended treatment rates are observed. In addition, even in the ITT analyses, the benefits of AF ablation in reducing atrial fibrillation burden[14] and improving quality of life[5] remain paramount in ablation decision making.

It is important to again note that atrial fibrillation is a burgeoning epidemic, and the tools for managing this disease are improving as well. Atrial fibrillation is very complex with each patient having different comorbidities, heart rhythm characteristics and preferences. ACC and HRS anticipate several studies on this topic in the coming months. We ask that UnitedHealthcare not implement its prior authorization rules for AF catheter ablation based on the CABANA trial's mortality and cardiac event results alone until the study can be assessed in conjunction with the forthcoming data.

MCG™ Care Guidelines
After expert clinician review, we recommend the Catheter Ablation Care Guidelines to include the following:

- **Asymptomatic atrial fibrillation patients with heart failure**
  In the randomized CASTLE AF trial of catheter ablation vs. medical therapy in patients with heart failure, catheter ablation was associated with a significantly lower rate of the composite end point of death from any cause or hospitalization for worsening heart failure than was medical therapy.[18]

- **Asymptomatic patients with persistent AF who do not accept permanent AF**
  Successful ablation improves exercise performance and quality of life in asymptomatic long standing persistent atrial fibrillation patients.[24]

We appreciate UHC and MCG acknowledging the importance of shared decision making and patient preference when deciding the management and treatment of atrial fibrillation. We strongly urge UHC to recognize that patient preference remains a priority for treatment choice.

In conclusion, the ACC and HRS appreciate your consideration of the above comments and welcome further discussion to help you understand the use of catheter ablation for atrial fibrillation in clinical practice. We ask that the prior authorization rules not add additional administrative burden to clinicians, and more importantly, do not interfere with the timing of patient care and the shared decision-making process between the patient and clinician when deciding whether to pursue catheter ablation or medication therapy. We are very much interested in working with you collaboratively to shed more light on AF ablation and how it fits in the therapeutic platform. For now, we request you not to move forwards with your restrictive prior authorization process.

Sincerely,

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President
American College of Cardiology

Christine M. Albert, MD, MPH, FHRS
President
Heart Rhythm Society

cc: Jaime Murillo, MD, FACC, FASE
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