From: Cog e, Chr stopher
Subject: Re: GAPMS process
To: ""Eng sh"","" Jeffrey; Jeffrey.Eng sh@ahca.myf or da.com
Sent: June 27, 2022 2:52 PM (UTC-04:00)

Thank you.

And thank you for standing up for the true credibility of the GAPMS process.

I will read the SOP attachment you sent and think about it more.

Your dedication and work are appreciated.

Chris

Christopher R. Cogle, M.D.
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From: English, Jeffrey <Jeffrey.English@ahca.myflorida.com>
Sent: Monday, June 27, 2022 2:30:05 PM
To: Cogle, Christopher <Christopher.Cogle@ahca.myflorida.com>
Subject: RE: GAPMS process

Good afternoon, Dr. Cogle,

There is a SOP for GAPMS.

Typically, the requests for consideration of coverage come in either through a health service research email address or from leadership (less often).

The GAPMS process exists to determine whether the service/device requested for coverage is "experimental/investigational" or "medically necessary".

The request gets run through the attached checklist, and once it is determined to be an actual GAPMS (rather than a decision point or "simple" coverage determination) I reach out to the requestor and schedule a time to gently walk them thru the process.

We ask that the requestor(s) send us a host of information, much of which is included on the checklist. They often send us published research about the service/device under consideration, relevant national or local coverage determination information, and as many examples as they have of coverage by other states or major insurers. The amount of information provided by the requestors can vary quite a bit in quality and completeness.

Their request is added to our GAPMS queue to be worked on, typically in the order in which they have been received. We do tend to reward requestors who maintain contact, provide updates, and respond in a timely manner to any inquiries we might have.

Assuming they check off all the boxes on the checklist, so to speak, we begin the process.

- I determine what similar services or alternative treatments we already cover. I verify that the service/device requested has FDA approval and a dedicated billing code.
- I utilize Policy Reporter to determine which states currently include the service/device on their respective fee schedules. I also research and verify any existing coverage among the major insurance companies. I look for any existing national or local coverage determinations.
- The greatest amount of time is spent researching the existing professional literature on the subject, ideally well designed, non-industry sponsored studies, in peer-reviewed journals. Systematic reviews and meta-analyses, when existing, play a big role and can often provide a heads up regarding the quality of the literature as well as any gaps that may exist. The quality can of course vary considerably depending on the item in question and how long it has existed as a treatment option. I also look for any existing clinical guidelines that might exist related to the request, as well as consulting various sites like AHRQ, Cochrane, NICE, etc. What do they have to say about it? Also, are their any ongoing trials identifiable through clinicatrials.gov that might shed more substantial light on the matter at a future date?
- I also pull any relevant articles pertaining to cost analyses that might indicate potential for cost saving for Florida Medicaid.
- Assuming (and for some of these that is a big "If") they check all the right boxes on all of the above, I will submit a request to MPF, along with a minimum of three price examples from other states that currently provide coverage, for a cost analysis. Anything added (with some exceptions) to the fee schedule must be budget neutral. So, we ask, what do we already pay for, can this new service/device offset any existing coverage, and does it lead to healthier outcomes at similar or less cost?

Once everything has been received, researched, and reviewed, I prepare a report that is roughly a template insofar as it is divided into sections ranging from "literature" to "existing coverage among other states" etc. Once the report has been completed, it goes to my immediate supervisor who reviews it for content and then forwards it to the Bureau Chief. Usually there would be a meeting with her, questions asked and answered, and then the report moves on to Tom for his signature, yay or nay, as final approval. Then the requestor is contacted and given a final copy of the report. If it is determined medically necessary and budget neutral, the code is then added to the fee schedule based on the normal fee schedule update timeline.

All of that is the ideal. The reality is that the reviews get done, the reports get written, and then they all bottleneck with leadership because GAPMS are fairly low on the totem pole of priorities, particularly since the pandemic began. It is also extremely common for a request to come in (most of them, really) that are asking for coverage long before the necessary information exists to justify coverage. Manufacturers will have a newfangled device with a tiny evidence base or will make the request before their most significant and enlightening trials/studies have even been completed. I have often said that a lot of what I am asked to look at will likely eventually gain coverage. But it is common for the request to outpace the evidence, and they are often several years away from finalizing their best case.

I believe there are currently about seven completed that are still awaiting review and approval from leadership. Some of them have been written for over two years. I have re-reviewed them and made any necessary updates concerning coverage, research, etc. I typically do that twice a year.

Of course, the requestors are always free to resubmit after a denial, so some of these never really die. But the resubmissions go to the back of the queue and are taken in the order they arrive.

If you will excuse me, I feel obligated to include this information: I was not informed or consulted, did not in any way participate, and did not write the GAPMS concerning gender dysphoria treatment. That particular GAPMS did not come through the traditional channels and was not handled through the traditional GAPMS process. Every report I have written represents my best effort at determining the most timely and accurate information available on the subject under consideration. I do not cherry pick data or studies and would never agree to if I were so asked. All I can say about that report, as I have read it, is that it does not present an honest and accurate assessment of the status of the current evidence and practice guidelines as I understand them to be in the existing literature. I sincerely apologize if I come across as a bit agitated about it, but as the "GAPMS guy" around here, lots of assumptions have been made by those

who do not know me well. I'm a different sort of person than the author of that report. I can't speak for them. I conduct myself and my work with integrity and I do not play favorites, yay or nay. Full stop, period.

Thanks so much for your help Friday. That shaved a few minutes off a tight deadline for me. Please let me know if you have any additional or questions or would like any additional information or clarification.

Take care.

Jeff

From: Cogle, Christopher <Christopher.Cogle@ahca.myflorida.com>
Sent: Saturday, June 25, 2022 9:13 PM
To: English, Jeffrey <Jeffrey.English@ahca.myflorida.com>
Subject: GAPMS process

Hello, Jeff. Good talking with you this past Friday.

Are there standard operating procedures for GAPMS?

If so, can I review them?

If no SOPs, then can I help you develop a SOP for GAPMS?

Thank you,

Chris

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