Sample Appeal Letter

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Via Priority Express Mail & Fax 859-425-3379
Aetna – Small Group and Middle Market (ISM) CRT
Attn: Daniel Kendis, Medical Director
P.O. Box 14002
Lexington, KY 40512

APPEAL OF ADVERSE BENEFIT DETERMINATION

Member: [redacted]
Plan Sponsor/Administrator: [redacted]
Member ID Number: [redacted]
Dates of Service: July 25, 2019 – September 18, 2019
Type of Service: Proton Therapy
Claim Numbers: Including, but not limited to, all claims listed in the attached chart of claims[1]

Dear Daniel Kendis, M.D.:

I am writing on behalf of your member, [redacted] who is covered under the [redacted] Plan (the "Plan"). Arthur has authorized Kantor & Kantor, LLP to act on his behalf in this matter. This letter serves as an appeal of Aetna's October 14, 2019 denial of [redacted]'s claims for proton beam radiation treatment ("PBRT") for prostate cancer. Please bear in mind that this October 14, 2019 letter clearly states that: "You . . .can ask us for a review (appeal) . . . in writing within 180 days (6 months) after you receive this letter." (AS_APPEAL_000274) Although Aetna dated this letter October 14, 2019, [redacted] did not receive this letter until October 19, 2019. One hundred eighty (180) days from October 19, 2019 is April 16, 2020. [redacted] submits this appeal letter and supporting documentation, on the attached thumb drive, well ahead of this deadline.

I want to emphasize one important and key fact in this letter. On July 10, 2019, just days before [redacted] started treatment his PSA was 13.2. As of February 2020, following completion of PBRT his PSA was 0.9. It is undisputed that [redacted]'s request for PBRT to treat his prostate cancer was not only medically necessary, not investigational/experimental and the most effective form of treatment [redacted] could have received bar none.

[1] Attached to the hard copy of this correspondence, please find a summary of all EOBs generated regarding Mr. [redacted]' PBT treatment at Hampton.

In support of [redacted]'s appeal, we are enclosing the following video and documents bates stamped [redacted]APPEAL 000001 to [redacted]APPEAL 0000805:

1. An executed copy of Aetna's Member Complaint and Appeal Form;

2. An executed copy of Kantor & Kantor's HIPAA Complaint Authorization for the Release and/or Discussion of Medical Records;

3. **A CD containing a short video created by [redacted] documenting his treatment and the outcome of his treatment**;

4. Correspondence between Aetna, Hampton University Proton Therapy Institute (HUPTI), and [redacted] organized in chronological order;

5. A copy of the [redacted] Plan;

6. Medical records from HUPTI relating to [redacted]'s diagnosis and treatment;

7. Howard Lee Jr., et al., *Early toxicity and patient reported quality-of- life in patients receiving proton therapy for localized prostate cancer: a single institutional review of prospectively recorded outcomes*, RADIATION ONCOLOGY (2018) 13:179;

8. Bryant, Curtis, et al., *Five-Year Biochemical Results, Toxicity and Patient-Reported Quality of Life After Delivery of Dose-Escalated Image Guided Proton Therapy for Prostate Cancer*, INTL. J. RAD. ONC. BIO. PHYS. (2016) 95:1;

9. Takagi, Masaru, et al., Long-term outcomes in patients treated with proton therapy for localized prostate cancer, CANCER MEDICINE (2017) 6:10;

10. Dutz, Almut, et al., *Early and late side effects, dosimetric parameters and quality of life after proton beam therapy and IMRT for prostate cancer: a matched-pair analysis,* ACTA ONCOLOGICA (2019) 58:6.

A. Factual Background

[redacted] is a [redacted]-year old man who was diagnosed with high-risk prostate cancer in December 2017. ([redacted]APPEAL_000036). In early 2019, [redacted] was diagnosed with prostate cancer. On February 11, 2019, his PSA read 9.5 and by July 10, 2019 it got as high as 13.12. In April 2019, proton beam therapy (PBRT) was prescribed as the most advantageous treatment for him and that would limit excess radiation doses to his bladder, small bowel, rectum and surrounding pelvic

tissues, thus preventing any worsening of his symptoms. ([redacted]APPEAL_000427). It does not appear from the current administrative record that Aetna considered or closely examined the individualized factor's underlying [redacted]'s diagnosis. Instead, it is apparent that Aetna's denials were predicated on the blanket application of an internal coverage policy to deny all claims for proton beam radiation therapy (PBRT) to treat prostate cancer.

[redacted] initiated a pre-service and post-service claim for PBRT to treat his prostate cancer. At each turn, Aetna has erroneously denied or upheld its denials of these claims on the same grounds that "[m]edical studies do not prove that this procedure is better than and as safe as other radiation treatment for prostate cancer." ([redacted]APPEAL_000225).

B. Relevant Plan Language

At two different snapshots in time it appears that Aetna applied two different plan provisions to deny [redacted]'s pre-service and post-service claims for PBRT. In its May 2, 2019 initial pre-service denial, Aetna appears to deny [redacted]'s request on the grounds that "[t]he plan does not cover experimental or investigational services except under certain conditions." ([redacted]APPEAL_000225). In its October 14, 2019 post-service claims denial, to which [redacted] now responds with this letter, Aetna appears to deny [redacted]'s request on the grounds that "[t]he plan does not cover services that are not medically necessary." ([redacted]APPEAL_000250).

1. Coverage for Randomized Phase II/III Clinical Trials – PBRT for Prostate Cancer

On May 1, 2019, Aetna sent a letter to [redacted]'s treating provider Hampton University Proton Therapy Institute ("HUPTI"), Dr. Christopher Sinesi, indicating that Aetna was "now considering coverage of proton therapy in the context of approved randomized phase II/III clinical trials." ([redacted]APPEAL_000215) This letter included coverage for a clinical trial, NCT01617161, for "Proton Therapy vs. IMRT for Low or Intermediate Cancer Risk Prostate Cancer (PARTIQol)." ([redacted]APPEAL_000216) To the degree that Aetna considered [redacted]'s treatment to be subject to a clinical trial that would meet Aetna's coverage requirements, [redacted] was entered into a clinical trial and a national registry. ([redacted]APPEAL_000217-224).

Based upon this May 1 letter, [redacted] was under the belief that he would be covered for his treatment. Ironically, the May 1 letter itself references Aetna's "hope that this positive change in coverage will promote access to proton therapy through participation in important clinical trials designed to demonstrate the possible benefits and harms of proton therapy, thereby removing insurance coverage barriers to trial participation." ([redacted]APPEAL_000216).

2. The Plan Defines "Clinical trial therapies (experimental or investigational) As Follows

Clinical trial therapies (experimental or investigational): Eligible health services include experimental or investigational drugs, devices, treatments or procedures from a provider under an "approved clinical trial" only when you have cancer or terminal illnesses and all of the following conditions are met: Standard therapies have not been effective or are not appropriate. We determine based on published, peer-reviewed scientific evidence that you may benefit from the treatment.

([redacted]APPEAL_000038).

On May 2, 2019, the very next day after [redacted] received the letter from Aetna regarding enrollment in a clinical trial, Aetna sent a letter to [redacted] denying his initial pre-service request "that there is no clear evidence that proton beam therapy for prostate cancer offers any clinical advantage over other forms of definitive radiation therapy." ([redacted]APPEAL_000225). Aside from being an untrue statement, Aetna employed quite the bait-and-switch within the span of 24 hours—first, it offered information about coverage for clinical trials of which it recommended to [redacted]'s treating provider, Dr. Sinesi, and then followed up with a denial of this request saying that there is not enough evidence to support coverage for PBRT. What exactly then was the point of the clinical trial, the letter regarding the clinical trial and the Plan's language regarding coverage for "clinical trial therapies?"

3. The Applicable Plan Defines "Experimental or Investigational" As Follows

Experimental or investigational
A drug, device, procedure, or treatment that is found to be experimental or investigational because:

- There is not enough outcome data available from controlled clinical trials published in the peer- reviewed literature to validate its safety and effectiveness for the illness or injury involved
- The needed approval by the FDA has not been given for marketing
- A national medical or dental society or regulatory agency has stated in writing that it is experimental or investigational or suitable mainly for research purposes
- **It is the subject of a Phase I, Phase II or the experimental or research arm of a Phase III clinical trial**. These terms have the meanings given by regulations and other official actions and publications of the FDA and Department of Health and Human Services
- Written protocols or a written consent form used by a facility provider state that it is experimental or investigational.