CLINICAL WHITE PAPER | MEHEE CHOI, MD AND BRIAN MARTIN, MBA

GAMMATILE® SURGICALLY TARGETED RADIATION THERAPY (STaRT)

Improving access to brain tumor care without compromising outcomes

ABSTRACT

Patients with brain tumors face enormous challenges after diagnosis. Many of these challenges are amplified by issues related to access to care.[1–4] Studies suggest that patients with cancer who live farther from radiation treatment centers have poorer clinical outcomes. In addition, minorities are more likely to perceive longer travel distances as a barrier, which may cause them to forgo needed radiation treatments.[1–4] To address these challenges, the Centers for Medicare & Medicaid Services (CMS) has identified improving access to healthcare for nonurban populations as a key policy priority.[5]

CURRENT STANDARD OF CARE

The current initial standard of care for aggressive brain tumors—either primary brain tumors (ie, tumors that originate inside the brain) or metastatic tumors (ie, tumors from cancers that originate outside of the brain)—is maximum safe surgical resection. After surgery, a follow-up treatment, also referred to as adjuvant treatment, is often recommended to help eliminate any residual tumor cells in or near the surgical resection cavity.[6] In the case of brain tumors, more often than not, adjuvant therapy involves using radiation.[6]

Adjuvant radiation is used either alone or in combination with chemotherapy, and the most common method of radiation treatment is external beam radiation therapy (EBRT).[6,7] For EBRT, specialized equipment, typically a linear accelerator, generates radiation beams and focuses them inward to travel through the skin, through the skull, and finally, into the brain.[7] Postsurgical wound healing must occur prior to the initiation of EBRT, which can delay radiation treatment for weeks and leave a window for unchecked cell replication and tumor recurrence.[8,9] In addition, if the tumor recurs and the patient has already received their maximum safe dose of EBRT, there may not be many other options for effective adjuvant therapy.[6,1]

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GammaTile Therapy is a safe and effective radiation option that requires no capital investment and eliminates the need for multiple treatment visits along with the associated transportation and caregiver burdens.[11–14]

To provide targeted brain EBRT, such as intensity-modulated radiotherapy (IMRT) and stereotactic radiosurgery (SRS), treatment centers must have both the significant fiscal capital equipment investment and the radiation oncologists with the expertise to treat brain tumors. Additionally, EBRT can require extensive postsurgical follow-up treatment, which means the patient must travel (sometimes daily for up to 6 weeks) to the radiation facility.

GAMMATILE | SURGICALLY TARGETED RADIATION THERAPY (STaRT)

FDA-cleared in 2018, GammaTile surgically targeted radiation therapy (STaRT) is a form of radiation therapy that is implanted by the neurosurgeon at the time of brain tumor removal. GammaTile Therapy is a safe and effective radiation option that requires no capital investment and eliminates the need for repeat treatments along with the associated transportation and caregiver burdens.[11–14] The therapy not only improves access to care, but it also ensures 100% compliance as patients can go about their daily lives as they receive their "built-in" radiation treatment. The safety and efficacy of GammaTile Therapy has been demonstrated in clinical studies and postapproval use.[11–14] It improves local tumor control in patients with recurrent meningiomas and recurrent brain metastases.[11–14] GammaTile Therapy exhibits the potential to extend overall survival in patients with recurrent glioblastomas.[11–14]

GammaTile Therapy is covered by Medicare and most private insurance. It is available in the United States, and can be easily adopted by any neurosurgery center equipped for craniotomies that has a radiation safety officer on staff.

ACCESS TO CARE

This paper identifies the number and locations of US radiation oncology centers with brain tumor treatment expertise, defined as centers with SRS experience for brain tumors. Next, the percentage of residents having at least 30-, 60-, 90-, and 120-minute drive times to these radiation oncology centers was calculated. The findings reveal that rural states have a disproportionally larger percentage of the population who live a longer distance from the identified radiation oncology centers. Also identified are the number and locations of US neurosurgery centers that bill for craniotomies, the procedure required to remove brain tumors, noting that they are centers with the expertise to provide GammaTile Therapy (ie, any facility that can perform a craniotomy is eligible to treat a patient with GammaTile Therapy). There are 135 radiation oncology centers with brain tumor treatment expertise vs 530 neurosurgery centers with the expertise to provide GammaTile Therapy. That is 4 times the number of neurosurgery centers than EBRT centers providing critically needed care. These 530 neurosurgery centers are more geographically dispersed, which could bring the option of GammaTile Therapy much closer to patients in rural areas. Broad adoption of GammaTile Therapy by neurosurgery centers across the country would expand their brain tumor treatment services, bringing a safe and effective treatment option to these currently underserved areas. This would simultaneously improve patient access to care without compromising clinical outcomes.

BACKGROUND

Patients with brain tumors face enormous challenges after diagnosis. Many of these challenges are amplified by access-to-care–related issues and the lack of options for adjuvant therapy.[1–4,6,10]

A comprehensive body of published literature firmly establishes that the burden of travel from a patient's house to a treatment center has a negative impact on adherence to treatment regimen, timeliness of treatment, prognosis, and quality of life.[1–4] Furthermore, these studies suggest that the poorer outcomes for patients living farther from treating hospitals is likely associated with poor patient compliance and follow-up.[1–4]

In a 2015 publication entitled *Challenges of Rural Cancer Care in the United States*, the lack of availability of radiation oncologists and radiation facilities in rural areas is identified as a critical concern.[2] In that article, several cited studies substantiate that rural patients receive less-curative radiation than urban patients.[2] In addition, they found that longer travel distances are associated with lower rates of guideline-indicated radiotherapy.[2] Because repeated visits for adjuvant radiation treatment after surgery are often necessary, distance and transportation logistics are critical hurdles that patients and their caregivers must navigate.[2] The extensive travel required for daily radiation treatments presents problems with respect to time lost from work and associated out-of-pocket costs, not to mention the psychological and physical toll that ongoing treatment can take.[2] Longer distances may present further obstacles to obtaining timely treatment or even cause patients to forgo radiation therapy.[2] Additional supporting evidence from a 2016 publication found a statistically significant decrease in rates of radiotherapy treatment for patients traveling more than 50 miles compared to those traveling less than 12.5 miles for their radiation treatments.[3]

With traditional EBRT techniques such as SRS as an adjuvant therapy for the treatment of brain tumors, access to care is limited. Patients with recurrent brain tumors who have received their maximum safe doses of EBRT may not have any other localized adjuvant treatment options.

A Guidry et al. study examining barriers to cancer treatment for patients reports that more than 50% of patients do not drive themselves to their radiation treatments and must rely on someone else or public transportation.[4] The distance to the radiation treatment center is a perceived barrier for Hispanic minorities (66%) and Black minorities (51%) vs white individuals (37%).[4] In addition, 62% of Hispanic individuals and 55% of Black individuals, vs 37% of white individuals, report that finding someone to drive them to their treatment is a barrier that could cause one to forgo treatment.[4] The authors conclude, **"Overall, the findings point to the transportation-related barriers that patients, especially minorities, may experience in obtaining needed medical treatment."**[4] Indeed, CMS has identified improving access to healthcare for nonurban populations as a key policy priority.[5]

With traditional EBRT as an adjuvant therapy for the treatment of brain tumors, access to care is limited by both the significant fiscal capital equipment investment as well as the select expertise of radiation oncologists familiar with this treatment. Additionally, EBRT treatments typically require the patient to travel to a site of care frequently if not daily, often over the course of several weeks. Notably, patients with recurrent brain tumors who have received their maximum safe doses of EBRT may not have any other options for adjuvant therapy.[6,10]

A safe and effective radiation option, GammaTile Therapy is implanted at the time of surgery by a

neurosurgeon at any neurosurgical operating room.[11–14] Unlike EBRT, GammaTile Therapy treatment begins immediately and continues as patients resume their daily lives. Consequently, GammaTile Therapy not only improves access to care, ensures 100% compliance and eliminates the need to travel for ongoing radiation treatments, it also provides an option for patients with recurrent brain tumors who have received their maximum safe doses of EBRT.[6,10]

METHODOLOGY

To determine patient access to care at centers that provide radiotherapy for brain tumor treatment, GT Medical Technologies analyzed CMS claims data on the following codes:

- CPT® code 77371: Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based
- CPT code 77372: Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based

Treatment under these codes requires both the fiscal capital to perform the procedure and the oversight of the appropriately trained radiation oncologist. The location of each institution that utilized these codes in 2018, as reported by CMS, was then mapped against the population of the United States.

Additionally, analysis was performed by state on the distance that the population has to drive to receive treatment at one of these centers. These calculations were based upon the estimated 2018 population data by ZIP code sourced from Data.gov and using a Google API tool to calculate driving times (30, 60, 90, and 120 minutes) from the radiation oncology centers identified through analysis of claims for codes 77371 and 77372.

Similarly, the company analyzed CMS claims data on DRG 023-027, which are the billing codes for craniotomies, the procedure required to remove brain tumors, which would make the facility eligible to treat a patient with GammaTile Therapy. The location of each institution that utilized these codes in 2018, as reported by CMS, was then mapped against the population of the United States.

RESULTS

US Radiation Oncology Centers With Brain Tumor Treatment Expertise

Through the analysis of claims, 135 centers were found to have actively utilized codes 77371 and 77372 in 2018. The centers in the continental United States are represented by the black dots on the map in **Figure 1**.

Drive Times to Radiation Oncology Centers With Brain Tumor Treatment Expertise

Analysis of drive times to these institutions produced the following results:

- **193 million Americans live 30 minutes or more from one of these centers.**
- **119 million Americans live 60 minutes or more from one of these centers.**
- **82 million Americans live 90 minutes or more from one of these centers.**
- **52 million Americans live 120 minutes or more from one of these centers.**

The percentage of residents by state for these drive times and the number of radiation oncology centers with brain tumor treatment expertise are shown in **Figures 2 through 5**. The color gradient depicts the percentage of the population who has an equal or longer drive time. The deeper and darker the red color, the greater the percentage of residents who must drive the stated number of minutes or more to receive treatment at the identified centers.

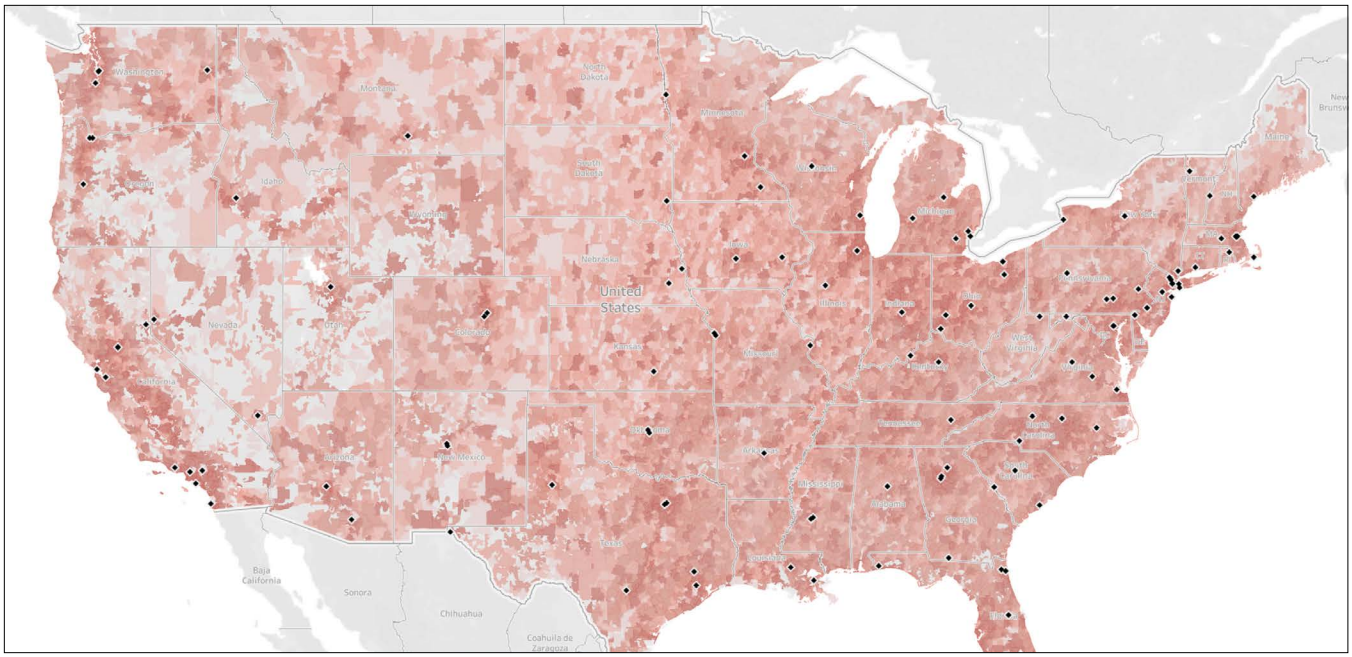

FIGURE 1. Radiation Oncology Centers With Brain Tumor Treatment Expertise vs US Population Density. *The black dots indicate the location of 135 centers that submitted SRS 1 or 5 fraction codes (77371 and 77372) for the treatment of brain tumors to CMS in 2018. The red gradient indicates the total population per the US government 2018 estimate. It should be noted that 2 states (Hawaii and Wyoming) did not have any centers reporting under these codes for SRS.*

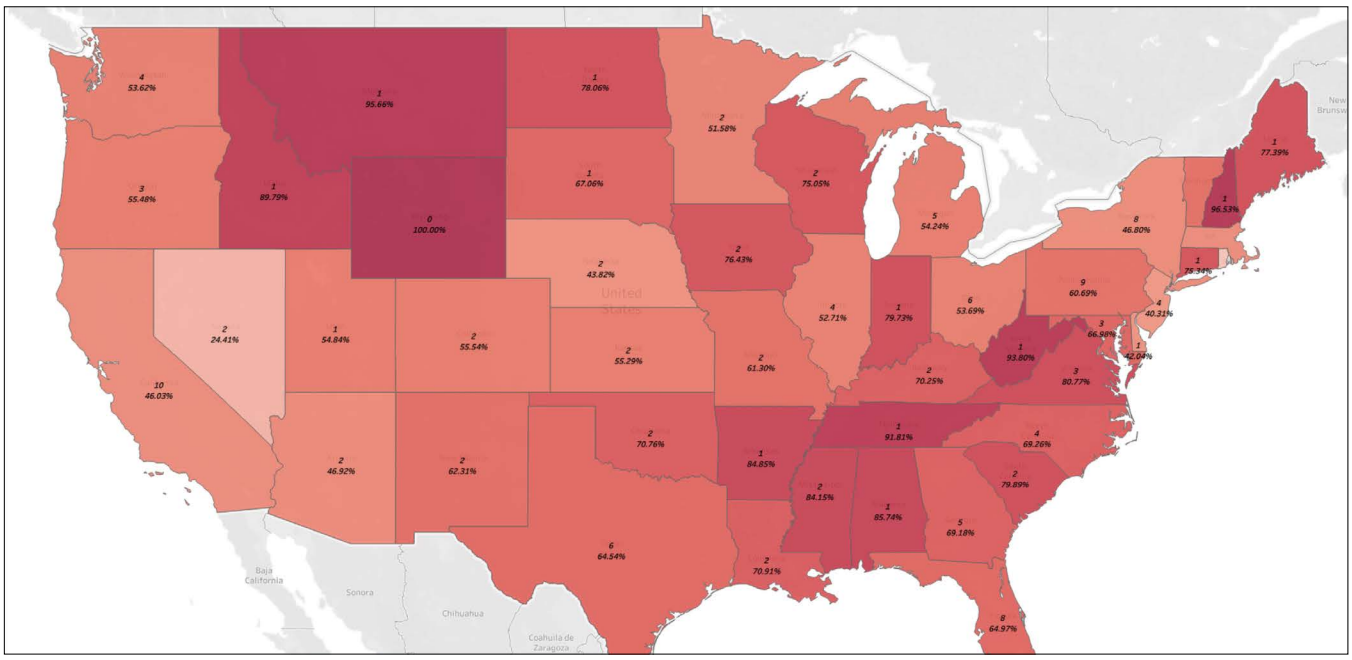

FIGURE 2. ≥ 30-Minute Drive Time to the Nearest Radiation Oncology Center With Brain Tumor Expertise. *The color gradient depicts the number of radiation oncology centers with brain tumor expertise and the percentage of the population who has a 30-minute or more drive time to the nearest radiation oncology center with brain tumor expertise. The deeper and darker the red color, the greater the percentage of residents who must drive ≥ 30 minutes to receive radiation treatment at the identified centers.*

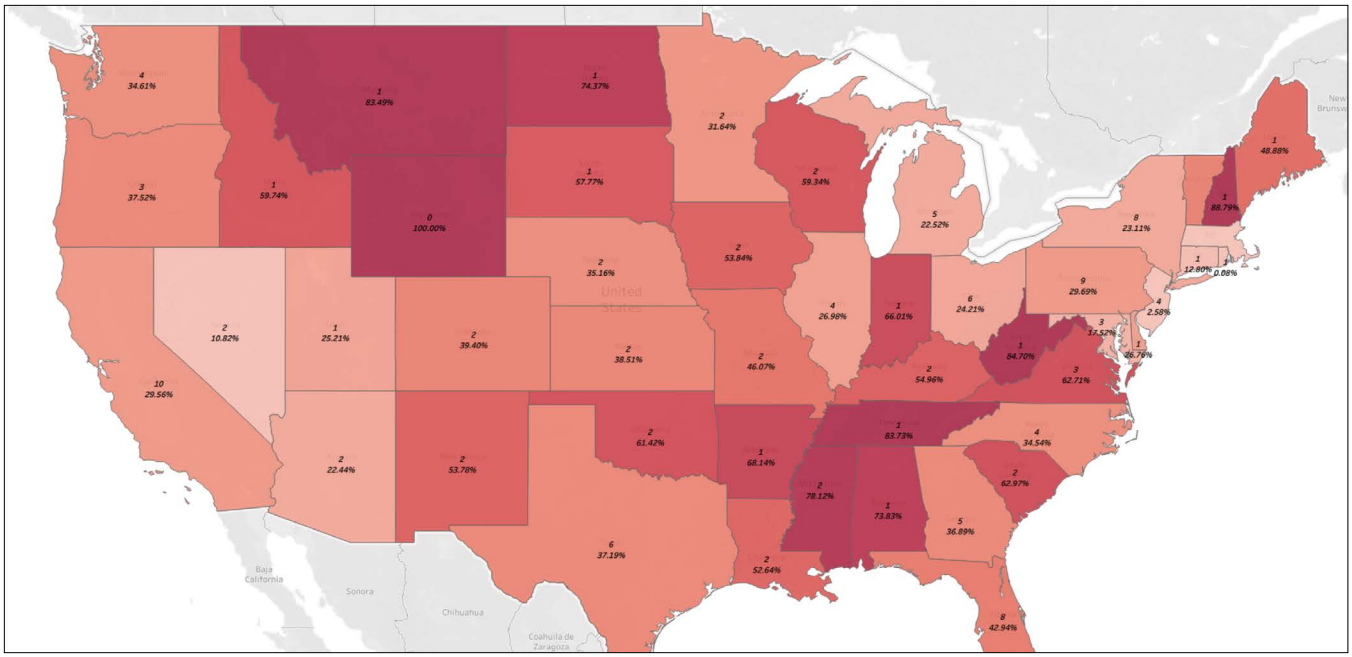

FIGURE 3. ≥ 60-Minute Drive Time to the Nearest Radiation Oncology Center With Brain Tumor Expertise. *The color gradient depicts the number of radiation oncology centers with brain tumor expertise and the percentage of the population who has a 60-minute or more drive time to the nearest radiation oncology center with brain tumor expertise. The deeper and darker the red color, the greater the percentage of residents who must drive ≥ 60 minutes to receive radiation treatment at the identified centers.*

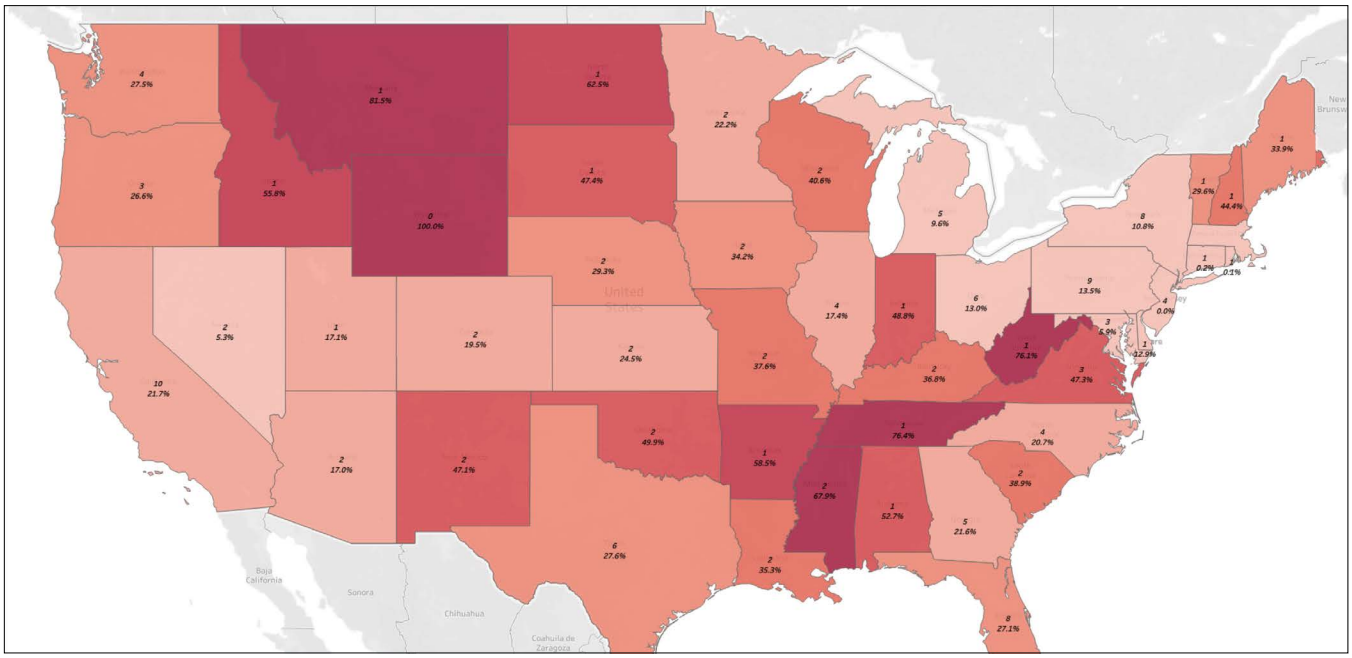

FIGURE 4. ≥ 90-Minute Drive Time to the Nearest Radiation Oncology Center With Brain Tumor Expertise. *The color gradient depicts the number of radiation oncology centers with brain tumor expertise and the percentage of the population who has a 90-minute or more drive time to the nearest radiation oncology center with brain tumor expertise. The deeper and darker the red color, the greater the percentage of residents who must drive ≥ 90 minutes to receive radiation treatment at the identified centers.*

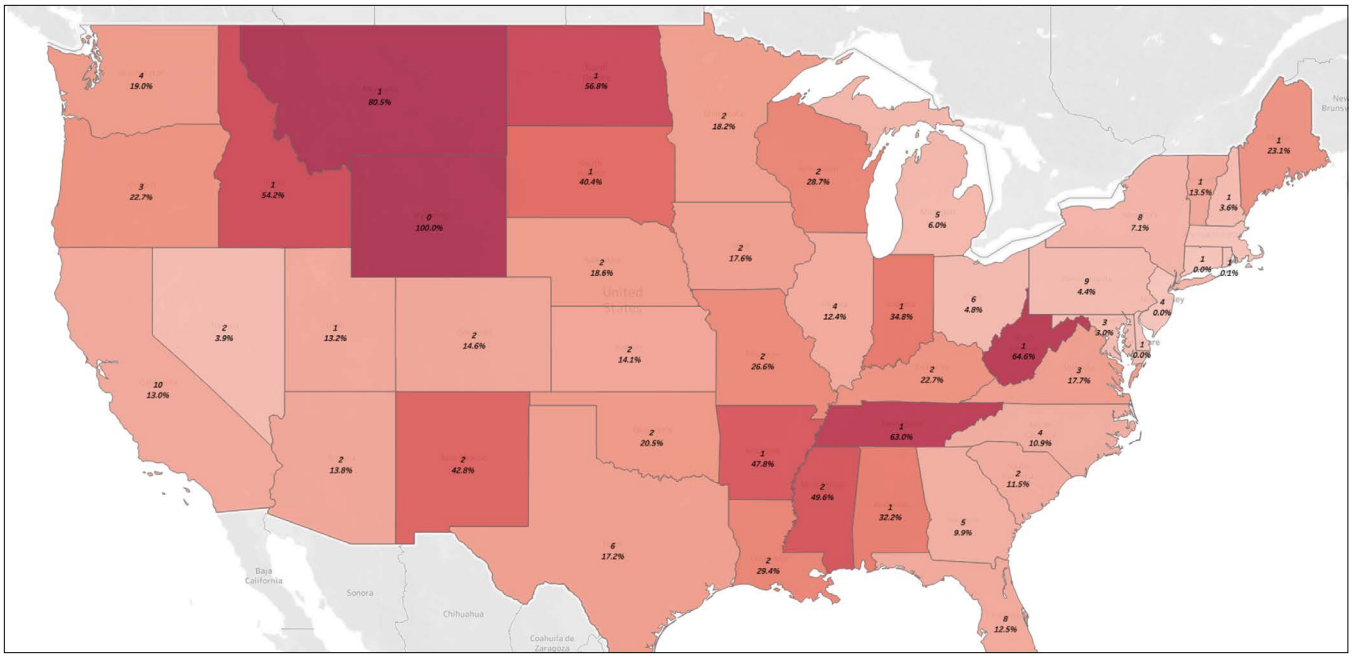

FIGURE 5. ≥ 120-Minute Drive Time to the Nearest Radiation Oncology Center With Brain Tumor Expertise. *The color gradient depicts the number of radiation oncology centers with brain tumor expertise and the percentage of the population who has a 120-minute or more drive time to the nearest radiation oncology center with brain tumor expertise. The deeper and darker the red color, the greater the percentage of residents who must drive ≥ 120 minutes to receive radiation treatment at the identified centers.*

Figures 2 through 5 demonstrate that rural states, particularly in the southeast, have a disproportionally larger percentage of the population who live a long distance from the identified radiation oncology centers. **Table 1** below provides specific data on key states without good access to care for their residents. For data on all states, provided as both the gross population and percentage of population, please refer to **Appendices 1 and 2**, respectively.

STATE	≥ 30 MIN	≥ 60 MIN	≥ 90 MIN	≥ 120 MIN
AR	85%	68%	58%	48%
AL	86%	74%	53%	32%
IN	80%	66%	49%	35%
LA	71%	53%	35%	29%
MS	84%	78%	68%	50%
MT	96%	83%	82%	80%
ND	78%	74%	63%	57%
SD	67%	58%	47%	40%
TN	92%	84%	76%	63%
WI	75%	59%	41%	29%
WV	94%	85%	76%	65%
WY	100%	100%	100%	100%

TABLE 1. Percentage (%) of Population by Drive Time to Radiation Oncology Centers With Brain Tumor Treatment Expertise by State

US Neurosurgery Centers With the Expertise to Provide GammaTile Therapy

Results from the CMS craniotomy DRG discharge data reveal that 530 institutions across the United States could perform GammaTile Therapy procedures, including at least one in every state. **Figure 6** shows the location of these hospitals relative to the US population.

Comparing **Figures 1 and 6** shows the much higher number of neurosurgery centers capable of providing GammaTile Therapy as well as the greater geographic dispersion compared to radiation oncology centers with the expertise to treat brain tumors.

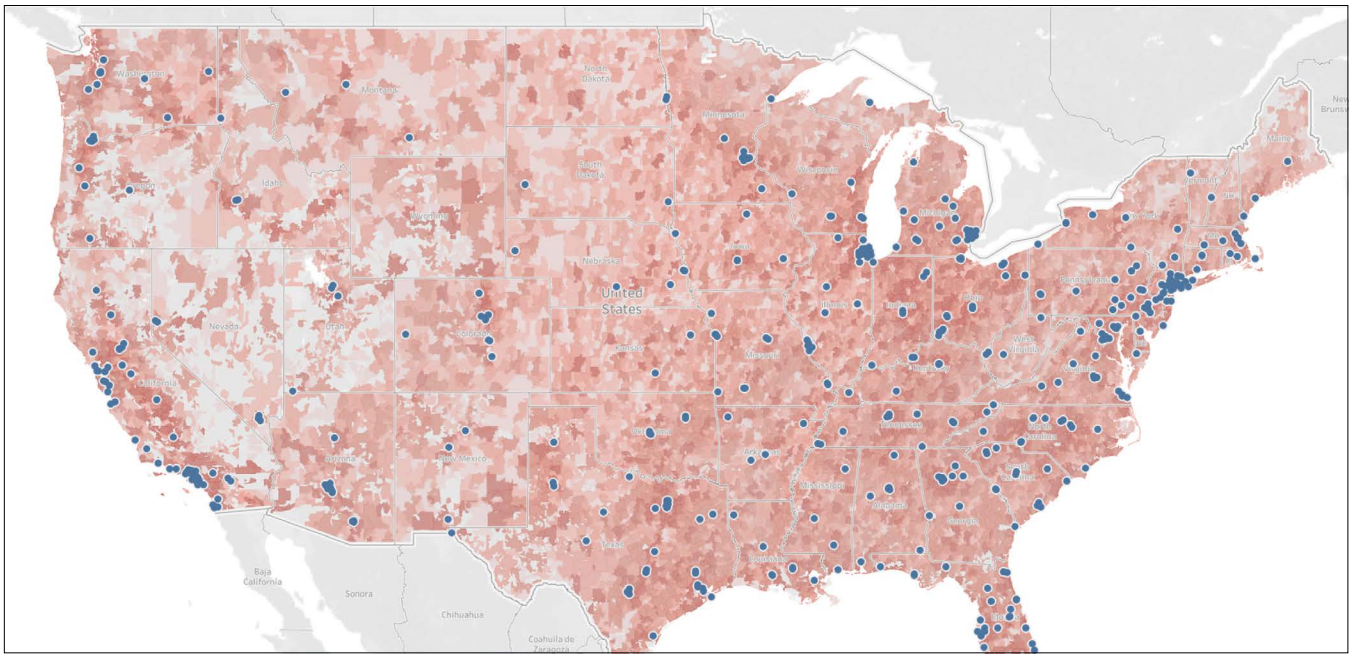

FIGURE 6. Neurosurgery Centers With the Expertise to Provide GammaTile Therapy vs US Population Density. *The blue dots indicate the locations of 530 centers that submitted claims on DRG 023-027, which are the billing codes for craniotomies, the procedure required to remove brain tumors. Any facility that can perform a craniotomy is eligible to treat a patient with GammaTile Therapy. The red gradient indicates the total population per the US government 2018 estimate.*

CONCLUSION

The case for making GammaTile Therapy more broadly available across the country, especially in rural areas, is clear, and offers benefits to both patients and hospitals.

Patients with brain tumors face a variety of challenges as they navigate their lives and therapy, including access to a care center, transportation logistics, compliance, and limited adjuvant radiation therapy options.[1–10]

GammaTile Therapy addresses these challenges head-on. First, it provides a safe and effective treatment alternative to repeat radiation treatments.[11–14] Implanted at the time of resection for immediate treatment, GammaTile Therapy ensures 100% patient compliance and does not require return trips for follow-up therapy. In addition, there are 4 times as many neurosurgery institutions that could utilize GammaTile Therapy compared to external radiation therapy centers with brain tumor treatment expertise. These 530 neurosurgery centers have a much greater geographic dispersion, which would bring a safe and effective brain tumor treatment to nonurban patients who might not have ready access to a radiation oncology center with brain tumor expertise.

The case for making GammaTile Therapy more broadly available across the country, especially in rural areas, is clear, and offers benefits to both patients and hospitals. It is imperative that the status quo standards of care be challenged. Access to care must be expanded and outcomes for patients with brain tumors elevated.

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APPENDIX

State	Centers	30	60	90	120
AK	1	498,294	359,789	358,084	354,321
AL	1	4,162,597	3,584,392	2,558,926	1,562,535
AR	1	2,515,310	2,019,918	1,733,680	1,416,547
AZ	2	2,882,866	1,378,733	1,044,435	844,958
CA	10	17,794,970	11,425,462	8,376,740	5,028,684
CO	2	2,956,071	2,096,867	1,040,488	778,542
CT	1	2,623,242	445,761	5,835	-
DE	1	399,143	254,103	122,778	-
FL	8	13,109,201	8,663,313	5,474,293	2,513,655
GA	5	7,014,299	3,739,691	2,187,690	1,006,138
HI	-	1,422,019	1,422,019	1,422,019	1,422,019
IA	2	2,363,067	1,664,458	1,058,102	542,639
ID	1	1,515,005	1,007,924	941,911	914,996
IL	4	6,582,050	3,368,747	2,170,191	1,552,438
IN	1	5,230,467	4,329,857	3,202,103	2,283,577
KS	2	1,608,066	1,120,014	713,962	411,326
KY	2	3,123,760	2,444,102	1,638,538	1,009,698
LA	2	3,306,883	2,454,783	1,644,187	1,373,233
MA	6	3,128,720	563,391	167,580	51,124
MD	3	4,007,291	1,047,977	351,302	182,257
MI	5	5,317,599	2,208,422	942,131	583,851
MN	2	2,841,775	1,742,894	1,224,401	1,002,981
MO	2	3,704,654	2,784,550	2,274,082	1,607,262
MS	2	2,514,907	2,334,635	2,030,140	1,482,239
MT	1	997,148	870,269	849,712	838,623
NC	4	6,964,652	3,473,478	2,078,777	1,094,883
ND	1	586,458	558,721	469,814	426,704
NE	2	834,698	669,730	557,169	354,132
ME	1	1,031,420	651,469	452,193	307,866
NH	1	1,287,584	1,184,343	592,611	48,323
NJ	4	3,579,997	229,030	-	-
NM	2	1,250,412	1,079,090	944,742	858,870
NV	2	639,580	283,520	140,158	101,978
NY	8	9,157,626	4,521,436	2,111,983	1,388,208
OH	6	6,250,027	2,818,122	1,515,230	560,111
OK	2	2,750,490	2,387,573	1,940,964	797,449
OR	3	2,179,393	1,473,883	1,043,233	893,603
PA	9	7,687,920	3,760,820	1,704,474	560,557
RI	1	164,598	827	827	827
SC	2	3,909,486	3,081,255	1,902,106	564,111
SD	1	503,757	434,026	356,435	303,291
TN	1	6,076,046	5,541,290	5,056,157	4,170,976
TX	6	17,859,280	10,291,565	7,638,534	4,762,395
UT	1	1,586,024	729,000	495,508	383,145
VA	3	6,713,448	5,211,912	3,934,077	1,472,273
VT	1	373,584	243,235	182,434	82,905
WA	4	3,805,142	2,456,267	1,949,357	1,350,925
WI	2	4,315,974	3,412,514	2,334,123	1,649,277
WV	1	1,669,765	1,507,859	1,354,766	1,150,770
WY	-	0	0	0	0
Totals	**135**	**192,796,765**	**119,333,036**	**82,288,982**	**52,047,222**

APPENDIX 1. Population by Drive Time (Minutes) to Radiation Oncology Centers With Brain Tumor Treatment Expertise by State

APPENDIX

State	Centers	30	60	90	120
AK	1	68%	49%	49%	48%
AL	1	86%	74%	53%	32%
AR	1	85%	68%	58%	48%
AZ	2	47%	22%	17%	14%
CA	10	46%	30%	22%	13%
CO	2	56%	39%	20%	15%
CT	1	75%	13%	0%	0%
DE	1	42%	27%	13%	0%
FL	8	65%	43%	27%	12%
GA	5	69%	37%	22%	10%
HI	-	100%	100%	100%	100%
IA	2	76%	54%	34%	18%
ID	1	90%	60%	56%	54%
IL	4	53%	27%	17%	12%
IN	1	80%	66%	49%	35%
KS	2	55%	39%	25%	14%
KY	2	70%	55%	37%	23%
LA	2	71%	53%	35%	29%
MA	6	46%	8%	2%	1%
MD	3	67%	18%	6%	3%
MI	5	54%	23%	10%	6%
MN	2	52%	32%	22%	18%
MO	2	61%	46%	38%	27%
MS	2	84%	78%	68%	50%
MT	1	96%	83%	82%	80%
NC	4	69%	35%	21%	11%
ND	1	78%	74%	63%	57%
NE	2	44%	35%	29%	19%
ME	1	77%	49%	34%	23%
NH	1	97%	89%	44%	4%
NJ	4	40%	3%	0%	0%
NM	2	62%	54%	47%	43%
NV	2	24%	11%	5%	4%
NY	8	47%	23%	11%	7%
OH	6	54%	24%	13%	5%
OK	2	71%	61%	50%	21%
OR	3	55%	38%	27%	23%
PA	9	61%	30%	13%	4%
RI	1	16%	0%	0%	0%
SC	2	80%	63%	39%	12%
SD	1	67%	58%	47%	40%
TN	1	92%	84%	76%	63%
TX	6	65%	37%	28%	17%
UT	1	55%	25%	17%	13%
VA	3	81%	63%	47%	18%
VT	1	61%	40%	30%	13%
WA	4	54%	35%	27%	19%
WI	2	75%	59%	41%	29%
WV	1	94%	85%	76%	65%
WY	-	100%	100%	100%	100%

APPENDIX 2. Percentage (%) of Population by Drive Time (Minutes) to Radiation Oncology Centers With Brain Tumor Treatment Expertise by State

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