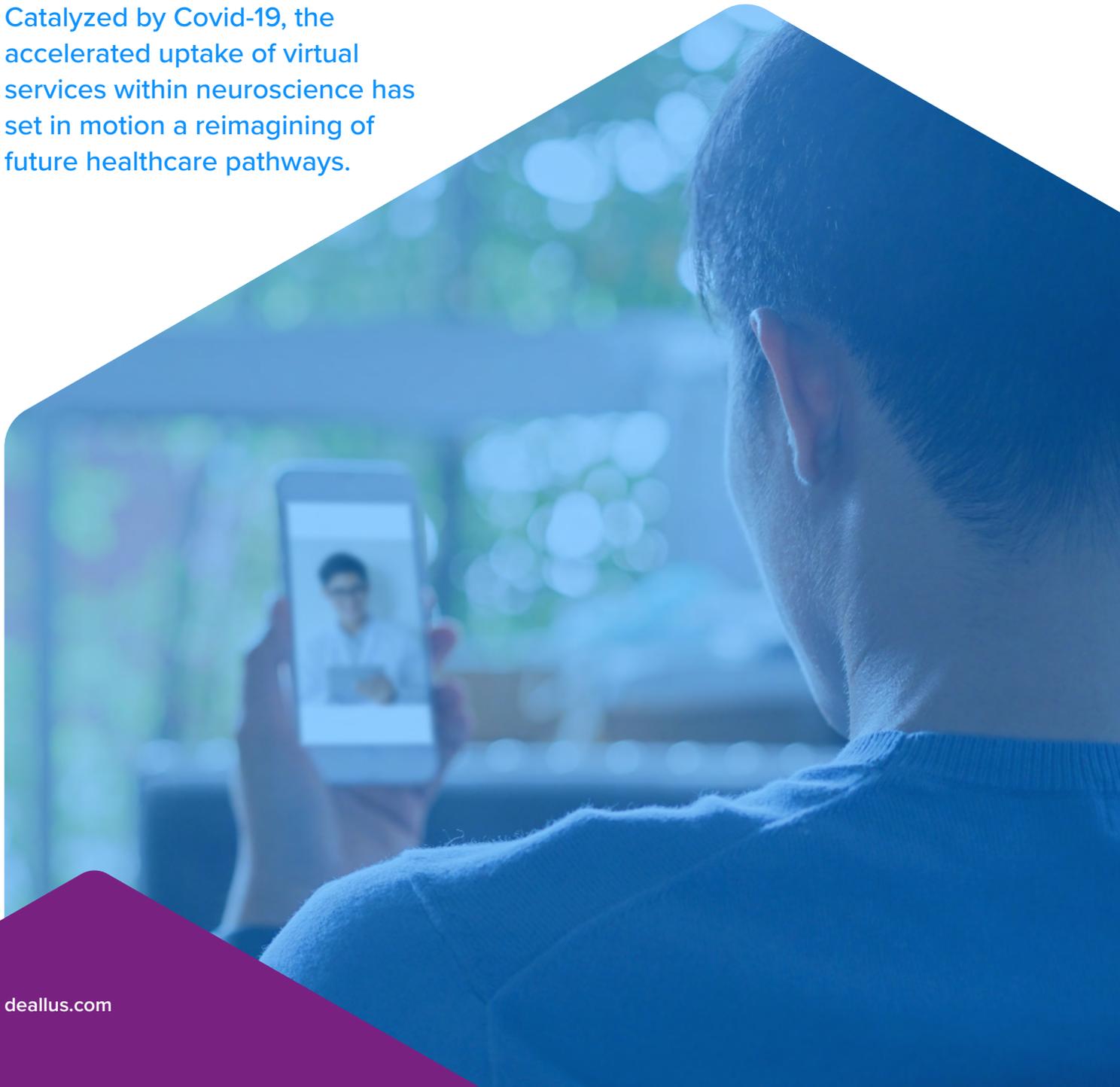


From bed-side to web-side: the future for telehealth & neuroscience in the U.S.

Catalyzed by Covid-19, the accelerated uptake of virtual services within neuroscience has set in motion a reimagining of future healthcare pathways.





Executive summary

In this white paper, we take an in-depth look at the rapid and recent adoption of telehealth, specifically in the field of neuroscience in the U.S.

- ▶ We may now be coming out of the acute pandemic phase, but our post-COVID-19 reality has been significantly and permanently changed by an evolution in the digital health technologies it drove.
- ▶ We examine the ramifications, opportunities, and challenges for healthcare providers, the pharma industry and manufacturers alike.
- ▶ Both healthcare providers and pharma companies are now operating in a new landscape and discovering new modi operandi to make connections with their patients and clients.
- ▶ Just as virtual engagement with pharma field reps is now here to stay, so too is the delivery of virtual treatment options for patients.
- ▶ The pandemic has presented all healthcare stakeholders with a wake-up call about the new solutions that digital transformation can offer in ensuring that the industry meets its existing and future challenges.
- ▶ Deallus has strong expertise in competitive intelligence monitoring of the neuroscience field and it explores how the pharma industry is adapting to the new landscape. In this paper, we share with you our telehealth findings and explore some of the wider consequences likely to be of relevance across the healthcare and pharma sectors.



The new post-pandemic reality is a hybrid virtual/in-person approach for many neurological and psychiatric conditions - driving rapid regulatory change, reduced delivery costs, and improved patient access.

Pre-COVID-19, the scheduling of an online visit for the treatment of a neurological or psychiatric disorder such as multiple sclerosis or depression was not common practice.

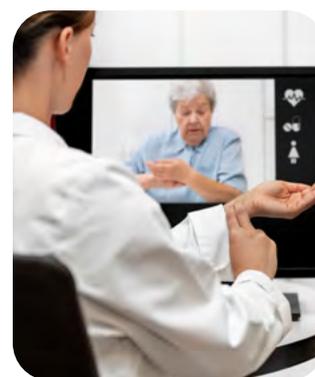
There were multiple disincentives for U.S. physicians to embrace telehealth (for full definition, see appendix: The telehealth spectrum).

First was the lack of 'approved' technology and the need to train staff and patients to use it. Second was the confusing labyrinth of Medicare and insurance reimbursement policies, federal agency regulations, and state-specific Medicaid rules.

But in March 2020, the entire U.S. healthcare system - from hospitals to physicians to first responders - was upended by the rapid and mass spread of COVID-19.

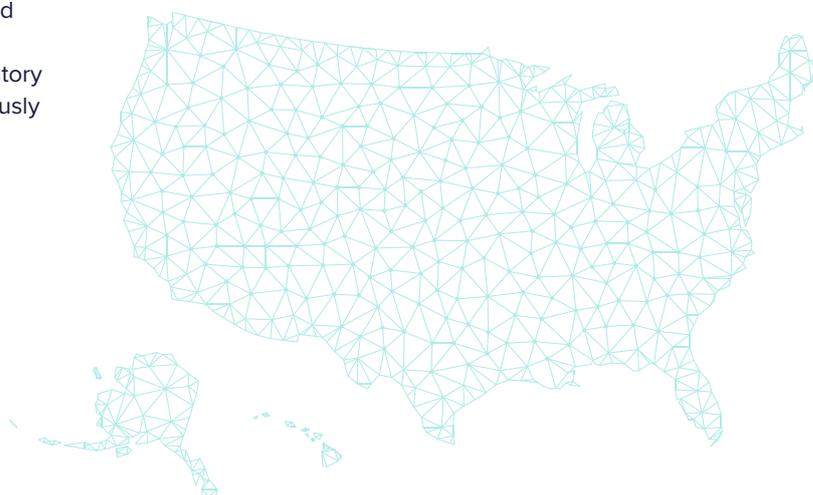
Healthcare providers hurriedly facilitated remote visits through phone, video - or any one of the mix of (now permitted) connectivity apps at their disposal - as necessity became the mother of invention to minimize virus exposure and safely deliver care.

During the pandemic, virtual consultations would prove to be the indispensable bridge to access healthcare, prompting a relaxation of the regulatory and reimbursement stipulations that had previously restricted its adoption.



And while today we know that telehealth is here to stay, there are still some elements of our new world which will take more time to become clear, including:

- ▶ The exact extent to which telehealth use will be sustained or offerings increased.
- ▶ Types of new technologies that will be developed specifically for telehealth delivery.
- ▶ Conditions for which telehealth may be further adapted to for clinical efficacy.
- ▶ Timing of any further permanent lowering of bureaucratic barriers.
- ▶ Ways in which pathways may be redesigned to combine in-person and virtual modalities.



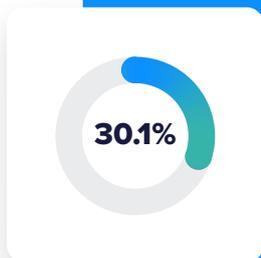


Telehealth overview by numbers during the pandemic in the U.S.



1 billion+

U.S. virtual healthcare interactions are expected across all indications for 2021-22¹



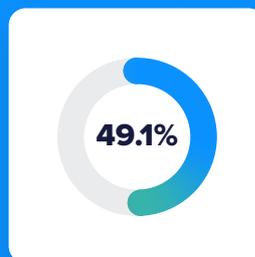
30.1% of total outpatient visits provided through telemedicine during the COVID-19 period.



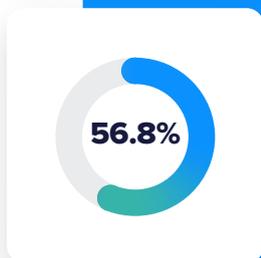
50.8% of total social work visits provided via telemedicine.



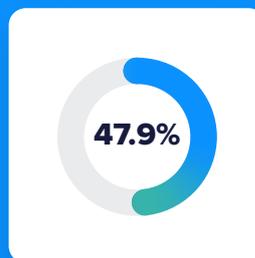
23-fold increase in telemedicine use over the pre-COVID-19 period.



49.1% of total psychology visits provided via telemedicine.



56.8% of total psychiatry visits provided via telemedicine.



47.9% of total neurology visits provided via telemedicine.

January 1, 2020, to June 16, 2020. January 1 to March 17 was designated as the 'pre-COVID-19 period' and March 18 to June 16 was designated as the 'COVID-19 period.'



A new era of health innovation

Major shifts in both provider and patient attitudes have proven powerful driving forces for the transition to telehealth we're seeing in both neurology and psychiatry.



Increased patient acceptance and growing adoption by physicians are behind the pivot towards more virtual care. Changes to the regulatory landscape are also set to roll out greater permanent access and simpler reimbursement ahead.

An array of mental and neurological disorders (MNDs) - including dementia, headache, multiple sclerosis and epilepsy - have been found to be compatible with the expanding application of telehealth tools and platforms.⁴ As the population continues to age, the prevalence of such disorders and associated costs will increase dramatically.

The U.S. economic burden of Alzheimer's disease alone was recently estimated at \$305 billion in 2020.³

Moreover, a recent study that shows that one-third of patients diagnosed with COVID-19 may develop psychiatric or neurologic disorders within six months, including depression, anxiety, strokes, and dementia.⁴

However, technological advances in healthcare - including telehealth - are promising avenues to alleviate this growing burden.

Virtual consultations, in general, are more cost-effective than in-office visits and can help reduce hospital admissions thanks to earlier intervention through at-home monitoring of symptoms and treatment adherence.

Telehealth may also help to counter the current large U.S. neurologist shortfall. Demand for neurologists is expected to grow by 19% by 2025. Expanding access to neuroscience care through telehealth could broaden the available demand to the current supply, by allowing more out-of-state practice to underserved areas.

A call for permanent telehealth expansion

The American Academy of Neurology (AAN) and the American Psychiatric Association (APA) are advocating for the continuation of telehealth post-pandemic.

"Telehealth services complement in-person neurologic care. The AAN supports patient access to telehealth services regardless of location, coverage for telehealth services by all subscriber benefits and insurance, equitable provider reimbursement, simplified state licensing requirements easing access to virtual care, and expanding telehealth research and quality initiatives."

The AAN, 2021

"Continued access to telehealth during and after the pandemic is vital. As we continue to face the long tail of the pandemic, we have an opportunity to innovate and continue to improve access through telehealth."⁵

The APA, 2021





American Psychiatric Association (The APA) survey findings



Nearly 6 out of 10 people are in favor of using telehealth for their mental health services.

(The percentage of Americans with this opinion increased from 49% in 2020 to 59% in 2021).



34% - more than one in three adults - say they "prefer a telehealth service to an in-person doctor's office visit."

(Up from 31% in 2020).⁶



81% of psychiatrists were continuing to see between 75 - 100% of their patient caseloads virtually by January 2021.

(Prior to the public health emergency 64% of psychiatrists were not using telehealth at all).⁵



33% of psychiatrists said they are now working with some patients who live in a different state from the one in which they practice.

(The APA survey finds spike in treatment demand, telehealth use).⁵

Patient and provider viewpoints

Most patients single out as the principal advantages of telehealth:

- ▶ Convenience and efficiency of communication and ease of access to care.
- ▶ Enhanced comfort for those with limited mobility due to their medical condition or need for home medical support equipment.
- ▶ Reduced travel costs and need to take time away from work or other essential activities for patients and care partners.

Most providers deem the principal advantages of telehealth as:

- ▶ A reduction in no-shows due to patients' easier access to care and decreased care costs.
- ▶ Benefits of early intervention through the ability to check in on a patient remotely (be it via monitoring devices that can track symptoms or send alerts or via a 'digital triage' telemedicine visit for assessment of neurologic disease progression in between regular scheduled in-person visits) can lead to better earlier intervention.
- ▶ Improved medication adherence resulting in fewer presentations to emergency departments and inpatient admissions.

Some patients view difficulties in access as a drawback to telehealth:

- ▶ Some populations that would benefit the most from telehealth - such as older adults or those living in rural or economically disadvantaged areas - are not yet able to gain access, mainly due to technology barriers, e.g. internet connectivity. However, despite barriers, older adults are adapting to this shift, and the number of Medicare beneficiaries using telehealth services grew drastically during the coronavirus pandemic. Between mid-March and mid-October, over 24.5 million out of 63 million beneficiaries had received a Medicare telehealth service.⁷

Some providers question the effectiveness of telehealth for patient physical assessment:

- ▶ For some neurological conditions, physical examination of gait and balance, and neuromuscular assessments to detect tremors, spasticity and weakness in the extremities are not feasible to conduct virtually, for now. Telehealth has been reported to be a barrier to clinicians' ability to manage drug-induced movement disorders (DIMDs).⁸ Although the authors acknowledged that multiple factors were at play in their study, they concluded that "in-person evaluation continues to be the gold standard for assessing and treating DIMDs."
- ▶ However, investments in monitoring technologies are already catalyzing the adoption of virtual care in the treatment of neurological and psychiatric conditions.



The telehealth regulatory and reimbursement revolution

Imagining that a new construct in healthcare would happen so fast was impossible pre-pandemic.

Telehealth adoption before the onset of the coronavirus outbreak was low - limited largely to a handful of private practitioners seeking flexible employment from telemedicine corporations.

But now, with virtual healthcare models and business models now at a point where they can facilitate a shift to permanent hybrid in-person/virtual care, the regulatory and reimbursement landscape is moving to catch up.

The Federal Government provided enhanced access to telehealth services during the pandemic, with many flexibilities tied to the temporary public health emergency (PHE) declaration. (See following page Telehealth and the changing regulatory landscape in the U.S.)

Regulatory changes that facilitated expanded use and simplified reimbursement have either already been made or are in the legislative process of becoming permanent.

These include legislation aimed at broadening telehealth access through grants for rural healthcare facilities, supporting behavioral/mental health telehealth services, and increasing broadband access.

More is likely to come, and there are dozens of proposed bills that will facilitate broader access to telehealth in the post-pandemic era.

These include the enhancement of store-and-forward reimbursement functionalities, requiring insurance to cover telehealth services as they would be covered in-person, and establishing the patient's home as an eligible distant site for telehealth care.

Most significant has been the (temporary) modification of the HIPAA (Health Insurance Portability and Accountability Act of 1996) requirements. A waiver now gives both patients and physicians the ability to use a HIPAA-compliant device and software that many already own such as a smartphone or laptop.

Uncertainty still exists, however, as to which waivers will remain when the PHE ends. Additionally, private insurance coverage varies across the board, with different sets of rules and dates for specific telehealth treatments they cover.

This leaves healthcare providers in limbo. In many cases, it is unclear whether they will lose telehealth payments when the PHE ends.



“I don't know what's going to happen after COVID... I think it [telehealth] will continue. And maybe people have hybrid practices... [Currently] telemedicine reimbursements are pretty much the same as in person. The worry is that after the pandemic, that the insurers won't do that anymore, and they'll sometimes penalize telemedicine, which would reduce its use. If they keep it the same as it is I think it will thrive...”

U.S. KOL



Telehealth and the changing regulatory landscape in the U.S.



HIPAA

Temporary update to permit unencrypted technology (e.g., Facetime, Zoom) to provide care.



Medicare and Medicaid reimbursement

Temporary recognition of a patient's home as an originating site and expansion of provider types, such as physical therapists.

Proposal from CMS would eliminate geographic restrictions and recognize the patient's home as an originating site in telemental health practice permanently.

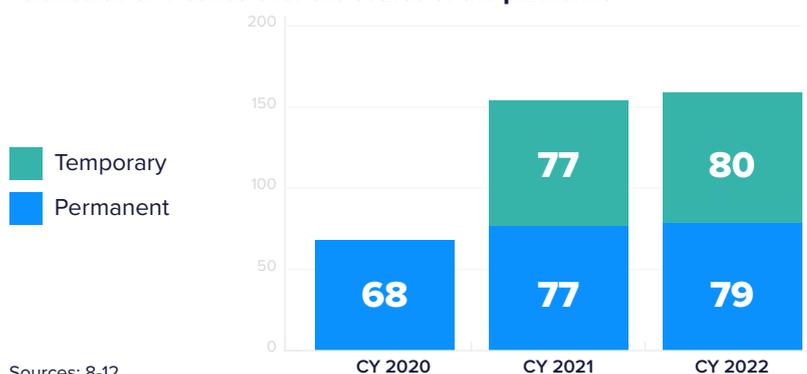


Coding and CPT management

COVID-19 has catalyzed the number of temporarily available Current Procedural Terminology (CPT) codes for neuroscience-related telehealth services. Proposed legislation may confer permanent status to some in the future.

CMS has already added permanent coverage for a range of services, including group psychotherapy, low-intensity home visits, and psychological and neuropsychological testing, among others.

Telehealth CPT codes over the course of the pandemic



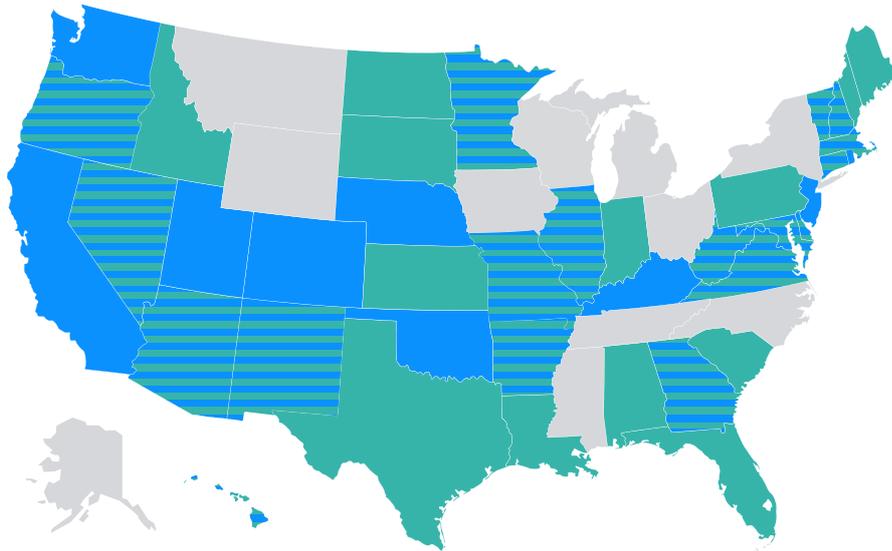
Sources: 8-12



Barriers to access



States with Permanent Payment Parity and Interstate Services



As of April 2022: States that have made permanent payment parity and interstate services¹³

- No
- Parity only
- Both parity and interstate services
- Interstate only

There are two types of parity requirements when it comes to telehealth laws:

- ▷ **Service parity:** requires the same services be covered via telehealth as would be covered if delivered in-person but does not guarantee the same rate of payment.
- ▷ **Payment parity:** requirement for the same payment rate or amount to be reimbursed via telehealth as would be if it had been delivered in-person.

Big differences are present between states, causing battles over state lines and licensing to impact patients' options:

- ▷ Nine states have passed permanent payment parity and interstate access legislation.
- ▷ 14 states have moved ahead of CMS and during the pandemic have approved the ability of neuroscience physicians to provide telehealth from outer state, including Arizona, Illinois, and West Virginia.
- ▷ 23 states provide permanent payment parity regarding telemedicine care, four of which have only approved payment parity for mental health disorder care and one has extended payment parity until mid-2023, with the possibility of making it permanent.

Private insurance

Due to the pandemic many private health companies shifted their telehealth reimbursement policies. For example, Aetna is paying physicians who conduct telehealth visits the same as their face-to-face rate. But, other insurers, among them Anthem and UnitedHealth Group, have already rolled back the payer parity policies in certain states.



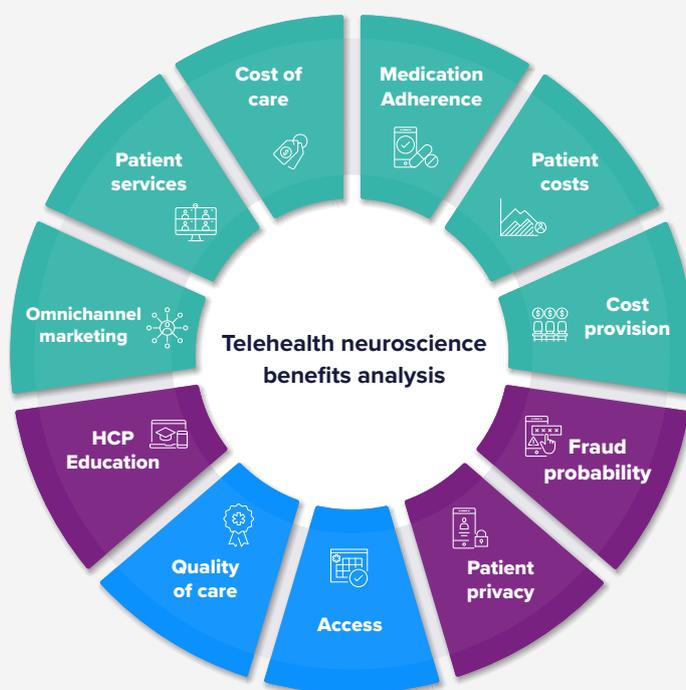
Opportunities for patients, HCPs, and manufacturers

Telehealth benefits those with neurological and psychiatric disorders by enhancing care through earlier intervention to prevent costly downstream care (e.g., hospitalization).

Additionally, telehealth care reduces auxiliary healthcare costs for patients, such as travel, and improves access to neurological and psychiatric care by increasing the availability of specialists for patients, especially those living in rural areas.

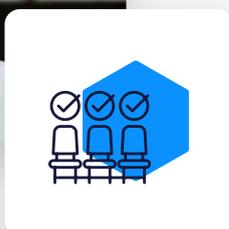
For healthcare practitioners, telehealth increases the available touchpoints with patients, which benefits medication adherence. Moreover, the overall cost to the healthcare system may be lowered by reducing the number of emergency care patients by catching people earlier in the disease progression and triaging those who are not critical to virtual care. Finally, the level of healthcare provided has been found to be similar with in-person care, suggesting personal preference of the HCP and patient will largely dictate the willingness to do virtual care.

Manufacturers are also able to enhance their patient services by being part of the virtual care experience, providing a unique opportunity to differentiate from competitors.



And, lastly, increased adoption of telehealth could yield greater awareness of and adherence to real-world monitoring initiatives, providing manufacturers that develop real-world monitoring tools with a trove of data that could shed light on new trends of disease progression.

In conditions like multiple sclerosis, several companies are developing technology to continuously monitor physical parameters remotely such as gait and balance, eye movement, and patient reported outcomes.^{14,15,16} So far, these technologies are early stage.



“Where it [telemedicine] affected was outpatient psychiatry... the no-show rates went to zero. So actually, psychiatry experienced a boom... not only did you have more people signing up, but also that they didn’t no-show. University clinics, which tend to take insurance, not cash, tend to see people on the worst insurances... So it’s a big hassle. And so you get a lot no shows. That all evaporated.”

U.S. KOL



A hybrid horizon for telehealth in neurology ahead

Will providers abandon telehealth and go back to business-as-usual pre-pandemic? The answer is: most certainly not.

Connectivity is transforming the healthcare industry to help HCPs and pharma companies optimise their existing technologies and processes.

At the same time, recent policies seem to favor telehealth accommodations, as evidenced by the recent move by Congress to grant a five-month extension (ending July 2022) to telehealth flexibilities stemming from the pandemic.¹⁷

The virtual gains from telehealth - greater access to care, and better and cheaper care - look likely to be a silver lining of the pandemic. But this does not come without caveats.

The application of telehealth for neurological and mental health conditions has been catalyzed by the pandemic, but the space is still rapidly evolving.

For some conditions, virtual care won't be initially applicable, but this will change as technology advances. In the clinic, where current practice guidelines were formulated for in-person care, and from a regulatory and reimbursement point of view, the lack of robust, longitudinal data on telehealth is a major limitation.

There is an acute need for randomized, controlled data to compare outcomes from in-person and telehealth, in particular for prevalent neurological conditions, such as Alzheimer's disease, migraine and multiple sclerosis. Finally, additional regulations are needed to reduce the threat of reimbursement fraud, to ensure patient privacy, and to increase equity of access to telehealth (i.e., adequate internet speed).

So, while it may be too early to say if telehealth will be the new frontline of care in these diseases, a likely scenario is further optimization of today's hybrid approach.

As in any industry undergoing disruption, adaptation will be necessary to capitalize on the new opportunities enabled by these changes - while at the same time avoiding potential pitfalls.

There are still challenges with how the pharmaceutical industry is adapting to the new normal of telehealth, for example:

- ▶ In what ways can telehealth enhance omnichannel marketing?
- ▶ In what ways can drug manufacturers utilize telehealth data to enhance their treatment offering?
- ▶ In what ways can leadership and expertise in telehealth strengthen your brand's position in the market?

The rate of change in this space over the past two years has been tremendous. In reality, we are only at the beginning, and the momentum behind this movement is incredibly powerful.

Telehealth - and the broader landscape of digital healthcare - is poised to revolutionize the pharmaceutical industry for decades to come. As industry leaders, the strategic direction that we set forth must align with this movement - or we risk being left behind.



The telehealth spectrum

Telehealth can be broadly defined as the delivery of healthcare services at a distance through the use of technology. It can include everything from conducting medical visits via video link to the remote monitoring of patients' vital signs.



Appendix

FEATURE	EFFECT	CASE IN POINT
Access	Varies	<ul style="list-style-type: none"> ▶ While the majority of Americans have access to the internet, gaps in technology access and use among some groups of patients remain. As of Feb 2021, approximately one-quarter of individuals in the US still lack fixed home broadband.¹⁸ ▶ While the lack of broadband access disproportionately affects rural areas, urban and suburban areas may also have subscribers who experience challenges getting online, like the cost of service or lack of suitable equipment for video calling.¹⁹ ▶ Older adults, the poor, communities of color, and patients who visit a community health center are all less likely to have the technology necessary to conduct a video visit. ▶ A recent study of more than 600 000 Medicare beneficiaries dwelling in communities from the 2018 American Community Survey demonstrated that 26% did not have access to either a computer with high-speed internet or a smartphone with a wireless data plan.²⁰ ▶ Non-English-speaking patients may be more hesitant to adopt telemedicine as an avenue for care.²¹
Adherence to Medication	Positive	<ul style="list-style-type: none"> ▶ The APA found telehealth (psychiatry specifically) improved medication compliance.⁵ ▶ A systematic literature review of 24 global randomized controlled trials demonstrated the improvement in patients' medication adherence and quality of life through the use of telehealth.²² ▶ A randomized pilot trial in veterans with multiple sclerosis showed improvement in behavior and medication adherence through brief tele-counseling, motivational interviewing and home telehealth monitoring.²³
Appointment attendance	Positive	<ul style="list-style-type: none"> ▶ A meta-analysis of no-show studies reported median no-show rates of 24% in neurology clinics.²⁴ However, a survey by Doctor.com: "Telemedicine Adoption in the Age of COVID-19 and Beyond" found 91% of participants believe telemedicine would help them stick to appointments, manage prescriptions and refills, and follow regimen recommendations.²⁵
Biomarker assessment	Varies	<ul style="list-style-type: none"> ▶ Some neurological disorders are difficult to develop accurate biomarkers for the clinic because of the absence of symptoms, such as Alzheimer's.²⁶ ▶ The currently utilized biomarkers could also be impractical for patients, for multiple sclerosis patients requiring MRI scans or a CSF IgG index.^{27, 28, 29} ▶ However, the use of mHealth sensors can assess symptom progression in real-time. This can be effective for neurodegenerative disorders, such as MS in which walking ability can be a biomarker to disease progression. By wearing sensors, physicians can collect data continuously in the background of everyday walking activities. Several labs are already conducting research into the use of these sensors, such as Boston Universities Neuromotor Recovery Laboratory.³⁰



Cost of care	Positive	<ul style="list-style-type: none">▶ Telemedicine looks likely to decrease spending for multiple neuroscience diseases such as multiple sclerosis that have costly and preventable downstream events, such as an emergency room visit, inpatient admission, or specialty referral.▶ Early intervention prior to a scheduled office visit, based on continuous assessment of neurologic disease progression and treatment efficacy of Parkinson's disease, is likely to reduce costs.³¹
Cost provision	Positive	<ul style="list-style-type: none">▶ The waiving of the HIPAA requirements has for now eliminated the cost of expensive equipment and Internet services (ranging from \$799 to \$1,099), formerly rated by 45% of physicians to be a barrier to telehealth.▶ Unlike expensive hospital systems, SaaS telehealth applications are low cost to implement. A systemic review found telehealth was shown to reduce costs to the health system in the short to medium term in 53%, 50%, and 32% of the cost-minimization, cost-effectiveness, and cost-utility studies reviewed, respectively.³²▶ A pre-COVID-19 study of 40,000 Cigna beneficiaries, the 20,000 beneficiaries who used the MDLive telehealth platform had a 36% net reduction in emergency department use per 1,000 people compared to non-virtual care users.³³
Fraud probability	Unmeasured	<ul style="list-style-type: none">▶ With increased telehealth activity comes increased chances for telehealth-related fraud. Without enhanced telehealth guidance from payers and government oversight, there will continue to be instances of fraud and abuse of telehealth services because it is a less regulated and relatively new industry.^{34,35}▶ High-quality interoperability measures will be invaluable to telemedicine.³⁶ But this requires standardization across the industry and dedication by stakeholders that don't currently have strong incentives.
Patients' costs	Positive	<ul style="list-style-type: none">▶ Savings in patients' costs for travel, childcare and time off work are an obvious benefit of telehealth.▶ Oregon Health and Science University state it has saved their patients \$6.4 million³⁷ annually in travel costs by implementing a telemedicine program offering consultations to various specialties.
Patient privacy and confidentiality	Unmeasured	<ul style="list-style-type: none">▶ Compared with face-to-face encounters, telehealth encounters are more vulnerable to privacy and security risks as no platform is 100% safe from hackers or data breaches.▶ In some cases, for people who cannot speak freely at home, confidentiality may be compromised.▶ However, several laws, including the Health Insurance Portability and Accountability Act, the Health Information Technology for Economic and Clinical Health, and the Children's Online Privacy Protection Act protect medical information for both face-to-face and telehealth encounters.
Quality of care	Equivalent	<ul style="list-style-type: none">▶ The ANA believes that on the whole telehealth offers "Improved access to expert neurologic evaluation", highlighting: "Better assessment of social determinants of health, including the patient's home environment" and "Increased care partner and provider participation during a visit."▶ ANA's paper Telemedicine in Neurology (2020) states: "Studies across multiple specialties report non-inferiority of evaluations by telemedicine compared with traditional, in-person evaluations in terms of patient and caregiver satisfaction. Evidence reports benefits in expediting care, increasing access, reducing cost, and improving diagnostic accuracy and health outcomes." It cautions however: "Many studies are limited, and gaps in knowledge remain."

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- All trade names, company names, and factual data used in this paper were verified correct at time of production.
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