MDForLives

THE GLOBAL PULSE OF HEALTHCARE · HOSPITAL ADMINISTRATION & EXECUTIVE LEADERSHIP INSIGHT REPORT

Hospital Readiness for High-Cost Therapies: Where Operational Risk Builds

Responses from hospital administrators and executives on the enterprise challenge of preparing for novel, high-cost therapies: how systems protect working capital, navigate payer rules, expand specialty capacity, schedule safety monitoring, govern formulary risk, choose sites of care, and decide which infrastructure must come next.

Financial Risk → Operational Capacity → Governance → Scale

20 Survey records	**3** Countries represented USA · Canada · Italy	**80%** Completion rate

WHY THIS REPORT

Novel therapies can reach approval faster than a health system can redesign the financial and operational machinery needed to deliver them.

For hospital administrators and executives, high-cost specialty therapies create a readiness problem that spans departments. A single launch can require multimillion-dollar acquisition planning, payer authorization, contracting, pharmacy and cold-chain capability, trained nursing, infusion capacity, diagnostics, safety monitoring, revenue-cycle workflows, formulary governance, and a decision about where in the network the therapy should actually be delivered.

External policy reflects the same complexity. CMS's active Cell and Gene Therapy Access Model uses outcomes-based agreements for sickle cell gene therapies and requires participating Medicaid programs to make reimbursement, operational, and coverage changes that support access. ASHP's current policy on cellular and gene therapies states that these products should be managed through the health-system formulary process, with pharmacy, service-line, finance, legal, informatics, supply-chain, and payment considerations treated as part of the medication-use system.

The MDForLives survey captures where hospital leaders see the friction now. Their responses point to a recurring tension: before access can scale, the organization must make the financial exposure predictable, secure specialized capacity, synchronize monitoring, create cross-functional governance, and choose an operating model that can support the therapy without destabilizing the wider system.

> **Methodology and data note.** Audience: hospital administrators and executives. Survey ID 8951420. The source report contains 20 survey records, an 80% completion rate, and respondents from the USA, Canada, and Italy. Country metadata contains 18 responses; the substantive closed questions contain 16 responses each. Administrative tracking, bad-ID, hidden required-text, after-question, and honeypot fields are excluded. The reader-facing report does not display a complete-response metric.

EXECUTIVE SUMMARY

Six signals that define high-cost therapy readiness

INSIGHT 01

Coverage certainty comes before acquisition

50.0% mandate strict upfront payer authorization and guaranteed coverage terms before acquiring extremely high-cost therapies.

INSIGHT 02

Reimbursement economics can block onboarding

37.5% say reimbursement or ASP markups that do not cover handling and administrative overhead create the greatest onboarding friction.

INSIGHT 03

Specialized nursing is the dominant throughput constraint

56.3% identify a shortage of appropriately trained nursing staff for complex monitoring and administration.

INSIGHT 04

Monitoring requires protected capacity

37.5% reserve fast-track diagnostic or imaging slots for specialty-therapy patients.

INSIGHT 05

Complex care is being centralized

50.0% prioritize dedicated Center of Excellence units at the main hospital campus for site-of-care growth.

INSIGHT 06

Pharmacy infrastructure leads the investment agenda

37.5% rank specialized pharmacy, cold-chain, and point-of-care manufacturing infrastructure as the most critical system investment.

01

WORKING-CAPITAL RISK

Before the drug reaches the hospital, half of executives want payer coverage locked down

50.0% mandate strict upfront payer authorization and guaranteed coverage terms before drug acquisition.

CONTEXT

Extremely high-cost therapies can move cash out of the health system long before the organization knows exactly when or how much it will be paid. For a finance team, this creates working-capital risk rather than a routine pharmacy-purchasing decision. The survey deliberately asks how systems protect themselves when single-dose acquisition costs can reach tens of thousands, hundreds of thousands, or more.

WHAT THE DATA SHOWS

Strict upfront payer authorization and guaranteed coverage leads at 50.0%. White or clear bagging models that shift inventory risk to an external specialty pharmacy are 25.0%. Traditional Buy-and-Bill supported by hospital reserves is 18.8%. Direct value-based or risk-sharing agreements with manufacturers are 6.3%.

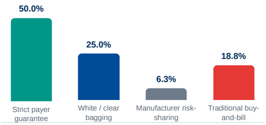
THE INSIGHT

The dominant strategy is risk avoidance before acquisition. Rather than buying first and resolving reimbursement later, the largest group treats payer confirmation as a financial gate. The relatively low selection of direct manufacturer risk-sharing suggests that sophisticated alternative-payment arrangements are not yet the default operational answer for these respondents.

WHY IT MATTERS

For executives, the therapy-launch checklist must include who can authorize capital exposure, what evidence is required before acquisition, how long receivables can remain outstanding, and what happens if coverage changes after treatment is scheduled. The financial control has to be designed before the clinical pathway goes live.

Primary financial strategy for extreme upfront therapy cost



02

PAYER ONBOARDING FRICTION

The hardest onboarding problem is not authorization alone. It is whether reimbursement covers the real cost of delivery.

37.5% identify low reimbursement rates or ASP markups that fail to cover handling, compounding, and administrative overhead as the most severe friction.

CONTEXT

High-cost specialty-therapy onboarding sits at the intersection of clinical eligibility and payer economics. Even after a therapy is approved, the health system may need to prove benefit coverage, satisfy payer-specific criteria, document medical necessity, resolve site-of-care rules, and determine whether reimbursement supports the cost of pharmacy, staffing, handling, and monitoring.

WHAT THE DATA SHOWS

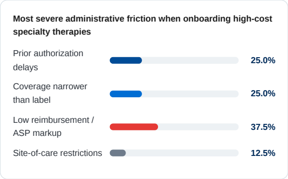
Low reimbursement or inadequate ASP markups lead at 37.5%. Protracted prior authorization review cycles and payer criteria narrower than FDA-approved indications are each 25.0%. Site-of-care restrictions are 12.5%.

THE INSIGHT

The pattern shows two types of friction operating at once. One determines whether the patient is authorized. The other determines whether the health system can deliver the therapy without losing money. A faster prior authorization decision is helpful, but it does not automatically fix an economically unsustainable payment rate.

WHY IT MATTERS

The operational model needs one workflow that connects coverage verification, contract terms, patient access, acquisition, billing, and expected reimbursement. If these steps are owned by separate teams with different data, a patient can clear the clinical gate while the financial gate remains unresolved.


Most severe administrative friction when onboarding high-cost specialty therapies

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03

THROUGHPUT CAPACITY

The service bottleneck is specialized nursing, which makes workforce availability a hard ceiling on growth

56.3% say specialized nursing shortages are the single greatest physical or operational throughput constraint.

CONTEXT

Complex infusions and advanced therapies often depend on nurses who understand product-specific administration, toxicity recognition, monitoring requirements, escalation pathways, and the operational choreography around pharmacy and diagnostics. That expertise cannot be created by adding infusion chairs alone.

WHAT THE DATA SHOWS

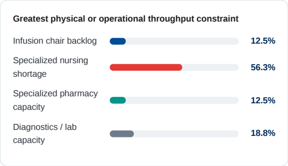
Specialized nursing leads overwhelmingly at 56.3%. Diagnostic imaging and laboratory capacity is 18.8%. Outpatient infusion chair availability and specialized pharmacy capacity are each 12.5%.

THE INSIGHT

The survey identifies labor as the system constraint with the greatest perceived effect on throughput. Physical capacity still matters, but respondents are more concerned about the people who can safely operate that capacity. This also changes the economics of expansion because recruitment, retention, competency, and scheduling become part of capital planning.

WHY IT MATTERS

Health-system leaders need to model throughput in terms of the scarcest required resource. A new therapy may need one infusion slot but several hours of specialized nursing, pharmacy verification, diagnostics, and post-treatment monitoring. Capacity planning should therefore be pathway-based rather than room-based.


Greatest physical or operational throughput constraint

04

MANDATORY SAFETY MONITORING

Safety monitoring becomes a scheduling problem when imaging, infusion, and follow-up use different queues

37.5% reserve dedicated fast-track diagnostic or imaging slots for specialty-therapy patients.

CONTEXT

Novel therapies can carry monitoring requirements that sit outside the treatment location itself. The survey examples include rapid MRI for ARIA, cytokine-management readiness, and cardiac toxicity screening. From an executive perspective, the recurring challenge is not the clinical rationale for monitoring but the logistics of making every required service available within the needed timeframe.

WHAT THE DATA SHOWS

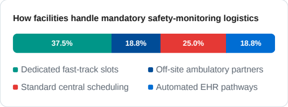
Dedicated fast-track diagnostic or imaging slots lead at 37.5%. Standard central scheduling that accepts possible delays is 25.0%. Off-site ambulatory partnerships and automated EHR pathways that synchronously book clinic, infusion, and diagnostics are each 18.8%.

THE INSIGHT

The most selected approach is to reserve capacity rather than rely on the general scheduling queue. That choice recognizes that safety monitoring can become a therapy prerequisite. If diagnostic capacity is unavailable, the treatment program is not truly available either.

WHY IT MATTERS

The highest-value redesign may be a therapy-specific scheduling bundle. When the treatment order is placed, the system should know which imaging, laboratory, infusion, toxicity-management, and follow-up slots must be protected, who owns exceptions, and how missed monitoring is escalated.



How facilities handle mandatory safety-monitoring logistics

05

FORMULARY GOVERNANCE

Novel-therapy decisions are moving above the service line because the risk is enterprise-wide

37.5% use a centralized executive panel spanning C-suite, pharmacy, finance, and medical leadership.

CONTEXT

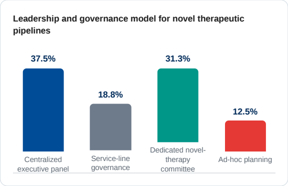
A high-cost therapy can affect patient access, pharmacy operations, contracting, capital, staffing, diagnostics, facility certification, revenue recognition, and strategic growth. That means the traditional clinical formulary decision can become an enterprise risk decision. ASHP's current policy on cellular and gene therapies explicitly supports formulary-system management with involvement from pharmacy and other health-system stakeholders, including finance, law, and informatics where appropriate.

WHAT THE DATA SHOWS

Centralized executive governance leads at 37.5%. A dedicated Precision Medicine and Novel Therapeutics interdisciplinary committee is close behind at 31.3%. Service-line governance is 18.8%, and ad-hoc operational planning is 12.5%.

THE INSIGHT

The two leading models are both cross-functional. The difference is where authority is housed: an enterprise panel or a specialized interdisciplinary committee. Only a minority leave decisions primarily within individual service lines or handle them case by case.



Leadership and governance model for novel therapeutic pipelines

WHY IT MATTERS

Governance should link the formulary decision to a readiness decision. Approval should trigger a clear view of payer exposure, pharmacy and cold-chain requirements, clinical competencies, diagnostic capacity, site-of-care rules, billing design, and launch ownership. Without that link, formulary approval can create a program the organization is not operationally ready to deliver.

06

SITE-OF-CARE STRATEGY

Executives are centralizing the most complex therapies before they decentralize access

50.0% prioritize dedicated Center of Excellence units within the main hospital campus.

CONTEXT

Site of care is both a clinical and strategic decision. Complex therapies may require concentrated expertise, pharmacy capability, diagnostics, toxicity management, and reimbursement knowledge. At the same time, health systems face pressure to bring care closer to patients and respond to payer-mandated movement into lower-cost settings.

WHAT THE DATA SHOWS

Center of Excellence units lead at 50.0%. Expansion of hospital-owned ambulatory infusion networks is 18.8%, partnerships with community-based physician groups or independent specialty practices are also 18.8%, and home infusion or Hospital-at-Home for maintenance dosing is 12.5%.

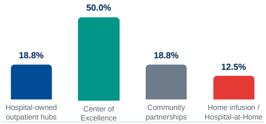
THE INSIGHT

The dominant strategy is concentration, not dispersion. Respondents appear to prefer a controlled main-campus model for the most complex therapies, while ambulatory, partner, and home settings remain secondary growth channels.

WHY IT MATTERS

A Center of Excellence can act as the system's learning environment. Once pharmacy, staffing, payer, diagnostics, monitoring, and governance workflows are stable, selected components of care may be extended outward. Decentralization is easier after the operating model is proven centrally.

Site-of-care strategy prioritized over the next 3 years



07

INVESTMENT PRIORITIES

The investment agenda starts with the physical medication pathway, then moves to digital authorization and specialized talent

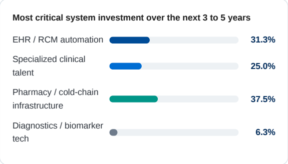
37.5% rank specialized pharmacy, cold-chain, and point-of-care manufacturing infrastructure as the most critical investment.

CONTEXT

Scaling high-cost therapies requires systems that can safely receive, store, prepare, track, and sometimes manufacture or manipulate complex products. It also requires digital tools that connect clinical eligibility with authorization and reimbursement, plus the workforce needed to operate the pathway.

WHAT THE DATA SHOWS

Specialized pharmacy and cold-chain infrastructure leads at 37.5%. Automated EHR clinical decision support and revenue-cycle management tools for prior authorization are 31.3%. Recruitment and retention of specialized clinical talent is 25.0%. Diagnostic and imaging upgrades are 6.3%.


Most critical system investment over the next 3 to 5 years

THE INSIGHT

The top two investments address two different failure points: physical product handling and digital financial workflow. Together they show that executives are thinking beyond traditional clinical capital. The ability to deliver the therapy and the ability to get it authorized and paid are both treated as core infrastructure.

WHY IT MATTERS

The best capital plan should map investment to the therapy pipeline. If multiple service lines will use the same pharmacy, cold-chain, prior authorization, or monitoring capability, enterprise investment may create more value than duplicating infrastructure inside each specialty.

08

CROSS-QUESTION FINANCIAL LENS

Payer uncertainty appears twice: first as a cash-protection strategy and again as the source of day-to-day administrative friction

50.0% require payer certainty before acquisition, while 37.5% say reimbursement economics create the greatest onboarding friction.

CONTEXT

The financial findings become more powerful when the working-capital and onboarding questions are read together. One asks how executives protect the organization before buying the therapy. The other asks what creates the most severe friction while bringing the patient onto treatment.

WHAT THE DATA SHOWS

In the financial-strategy question, 50.0% use strict payer authorization and guaranteed coverage before acquisition. In the onboarding question, 37.5% identify inadequate reimbursement or ASP markups as the biggest friction, while prior authorization delays and narrow coverage criteria each account for 25.0%.

50.0%

Require payer authorization and guaranteed coverage before acquisition

37.5%

Identify inadequate reimbursement economics as the largest onboarding friction

THE INSIGHT

The survey therefore distinguishes coverage certainty from payment adequacy. A payer can approve treatment and the health system can still face a poor economic result if reimbursement does not reflect pharmacy, administrative, monitoring, or site-of-care costs. The open-ended responses reinforce this distinction with comments about delayed billing rules, denials, uncertain contracts, uncompensated acute-setting costs, and upfront cash exposure.

WHY IT MATTERS

Executives need visibility across the entire cash conversion cycle, not just authorization status. Launch dashboards should track acquisition timing, authorization status, expected reimbursement, contract exceptions, denial risk, days in receivables, and patient financial exposure so the organization can see where access risk is becoming balance-sheet risk.

09

ENTERPRISE READINESS MODEL

The scalable model is not one new department. It is a synchronized operating system across finance, pharmacy, clinical operations, diagnostics, and governance.

The strongest signals converge on four enterprise resources: specialized nursing, centralized complex-care delivery, pharmacy infrastructure, and payer-connected digital workflow.

CONTEXT

Each survey question looks at a different piece of the health system, but the operating model is the connection between them. Finance controls acquisition risk. Revenue cycle manages payer friction. Nursing, pharmacy, infusion, and diagnostics determine throughput. Governance decides whether the organization accepts the risk. Site-of-care strategy determines where expertise is concentrated. Digital systems coordinate authorization, scheduling, and monitoring.

WHAT THE DATA SHOWS

The largest direct signals are 56.3% for specialized nursing as the top throughput constraint, 50.0% for Center of Excellence site-of-care strategy, 37.5% for specialized pharmacy and cold-chain investment, and 31.3% for EHR clinical decision support and revenue-cycle automation. These are separate survey responses, not a combined score.

THE INSIGHT

Together, the findings describe a platform approach to novel therapies. The hospital does not become ready because one committee approves the drug or one service line trains staff. It becomes ready when capital, payer, pharmacy, workforce, monitoring, and site-of-care decisions are linked to the same launch process.

WHY IT MATTERS

That shift changes executive planning. Readiness can be managed as a repeatable enterprise capability with defined gates: evidence and formulary review, financial and contracting review, site and capacity review, staffing and competency review, monitoring and emergency-readiness review, revenue-cycle build, launch, and post-launch performance tracking.

56.3%
Specialized nursing is the dominant throughput constraint

50.0%
Center of Excellence is the leading site-of-care strategy

37.5%
Specialized pharmacy and cold-chain infrastructure leads future investment

31.3%
EHR and revenue-cycle automation ranks second in future investment

OPEN-ENDED PERSPECTIVE

Executives describe the nightmare as uncertainty that crosses finance, payer policy, and operations at the same time

The open-ended question asked for the single biggest operational, financial, or payer-related nightmare the executive team faces when preparing the health system for a newly approved high-cost therapy. All 16 visible responses were reviewed qualitatively. The responses include English and Italian comments. Themes below are descriptive and are not assigned percentages.

Payer uncertainty and denials

Multiple responses describe coverage limbo, step edits, prior authorization, vague coverage determinations, retroactive audits, denials, changing insurance rules, and patient eligibility that is difficult to predict. The payer problem is described as unstable rather than merely slow.

Upfront cash and reimbursement exposure

Executives describe having to buy very expensive drugs before payment is guaranteed, absorb costs in capitated or acute settings, manage uncertain reimbursement rates, and carry the risk that payment delays or denials create significant cash pressure.

Staffing, scheduling, and approval capacity

Several comments condense the challenge into staffing, scheduling, cost approval, and operational coordination. These comments align with the structured finding that specialized nursing is the dominant throughput constraint.

Contract and site-of-care complexity

One detailed response highlights payer fragmentation, outcomes-based contracts, site-of-care and DRG mismatches, and time compression in approval. Other comments mention multiple payer contracts and life-cycle management contracts.

Communication and patient affordability

Minority views: budget and prescribing discipline

Communication appears directly as a concern, while other responses describe the need to chase grants or charity funding because patient out-of-pocket costs remain unaffordable even when coverage exists.

A smaller number of responses point to budget restrictions, changes in therapy based on generic availability, and broad prescribing without specific indications. These comments add a stewardship perspective to the dominant payer and cash-flow narrative.

> **What the qualitative responses add:** the executive fear is not simply that a therapy is expensive. It is that acquisition, approval, reimbursement, scheduling, patient affordability, and operational readiness can all remain uncertain at the same time, while the clinical pressure to treat continues.

HOSPITAL EXECUTIVE READINESS LENS

What a repeatable high-cost therapy launch model could look like

The survey does not prescribe one operating model. It does show which enterprise capabilities hospital leaders may need to connect before launch.

1. Financial and payer gate

Confirm coverage pathway, acquisition exposure, contracting assumptions, expected reimbursement, denial risk, and patient financial support before the therapy is scheduled.

2. Capacity and competency gate

Verify specialized nursing, pharmacy, infusion, diagnostics, monitoring, emergency-response capability, and staff competency for the specific therapy pathway.

3. Governance and site-of-care gate

Define who can approve enterprise risk, where treatment should occur, which elements can be decentralized, and what criteria trigger expansion beyond the initial Center of Excellence.

4. Digital and performance gate

Build EHR, authorization, scheduling, monitoring, revenue-cycle, and reporting workflows before launch, then track access, denials, throughput, safety, and financial performance after launch.

PEOPLE ALSO ASK

Frequently asked questions about hospital readiness for high-cost therapies

What are the main financial risks to hospitals offering high-cost therapies?

Key risks can include large upfront acquisition costs, uncertain or delayed reimbursement, payer denials, contract complexity, site-of-care restrictions, and mismatches between the cost of delivering therapy and the payment received.

How do hospitals manage working capital for cell and gene therapies?

Health systems may use strict coverage verification before acquisition, payer contracts, manufacturer arrangements, specialty-pharmacy models, dedicated financial review, or other risk controls. The right approach depends on the therapy, payer mix, reimbursement model, and local regulation.

Why can prior authorization delay access to high-cost specialty therapies?

High-cost therapies often require detailed eligibility, documentation, medical-necessity review, benefit verification, and payer-specific criteria. When requirements differ by payer or change after approval, administrative work can delay treatment even after a clinical decision is made.

What infrastructure is needed to deliver complex cell and gene therapies?

Needs vary by therapy but can include specialized pharmacy and cold-chain capability, trained nursing and pharmacy staff, infusion capacity, diagnostic and laboratory access, emergency and toxicity-management pathways, scheduling coordination, and robust financial and data systems.

What is a Center of Excellence for complex therapies?

A Center of Excellence is a concentrated program that brings specialized clinical teams, pharmacy, diagnostics, operations, governance, and financial processes together for complex care. The exact designation and requirements vary by health system and therapy.

How can health systems scale novel therapies safely across a network?

Scaling usually requires clear governance, standardized patient selection and authorization workflows, defined sites of care, trained staff, reliable pharmacy and diagnostic capacity, financial risk controls, and data systems that coordinate treatment and monitoring across teams.

CLOSING PERSPECTIVE

The next novel therapy does not create one new workflow. It

tests whether the entire health system can move as one.

The survey shows that hospital leaders are already thinking beyond the drug itself. Their decisions are shaped by whether coverage is guaranteed before acquisition, whether reimbursement reflects the real cost of delivery, whether specialized nurses and diagnostics can absorb demand, whether safety monitoring can be scheduled reliably, whether governance is strong enough to accept enterprise risk, and whether the therapy belongs in a centralized Center of Excellence or a broader distributed network.

The financial findings are especially important because they separate two problems that can be easy to collapse into one. First, the organization needs to know whether the patient is covered before it commits cash. Second, it needs confidence that the reimbursement will actually cover the therapy and the operational work around it. A positive authorization does not eliminate working-capital risk, underpayment, contract ambiguity, or site-of-care mismatch. The open-ended responses repeatedly return to this gap between clinical approval and financial certainty.

The capacity findings reveal a similar distinction. Physical infrastructure matters, but specialized nursing is the most prominent constraint. That means a capital plan built around new infusion space can still fail if the system cannot recruit, train, retain, and schedule the people who make complex therapy delivery safe. Diagnostic capacity also matters because mandatory safety monitoring can create a parallel queue that competes with routine imaging and laboratory demand.

Governance and site-of-care strategy show where organizations may be heading next. Centralized executive or interdisciplinary committees allow pharmacy, finance, medical leadership, and operations to evaluate the therapy as one enterprise decision. Center of Excellence models then concentrate expertise and control while the organization learns the pathway. Over time, selected services may move into ambulatory, community, or home settings, but decentralization works best when the central model is already stable.

The future investment priorities reinforce that operating model. Specialized pharmacy and cold-chain infrastructure comes first, closely followed by EHR and revenue-cycle automation. That pairing is telling: health systems need to manage both the physical product and the digital financial pathway. Neither can be treated as secondary infrastructure when a single therapy can create high clinical value and high organizational exposure at the same time.

1 · Make therapy readiness an enterprise gate

Do not allow clinical adoption to move ahead of payer, finance, pharmacy, staffing, diagnostics, and site-of-care readiness.

2 · Separate authorization from economic viability

Track whether a therapy is covered and whether the contracted reimbursement actually supports the cost of delivery.

3 · Model the scarcest resource

Plan throughput around specialized nursing, pharmacy, diagnostics, and monitoring, not only treatment-room capacity.

4 · Build therapy-specific scheduling

Protect imaging, laboratory, infusion, clinic, and follow-up capacity when timing is part of safe administration.

5 · Centralize first, then decentralize deliberately

Use a Center of Excellence to stabilize the operating model before extending selected services across the network.

6 · Measure access and financial performance together

Track time to treatment, authorization outcomes, denial reasons, utilization, patient affordability, receivables, and contribution margin as one launch dashboard.

Help future hospital leadership insights reflect the decisions behind complex therapy access.

Share your perspective with MDForLives and help build a clearer view of payer risk, operational readiness, capacity, governance, site-of-care strategy, and investment across health systems.

Join the Panel

Sources used for this report

1. **MDForLives Hospital Admin Insight Survey_Aug, SGID 8951420.** Source report: 20 survey records, 80% completion rate, respondents from the USA, Canada, and Italy, substantive closed-question base of 16, and 16 visible open-ended executive responses. Administrative and validation fields were excluded.
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